UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, and GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, on behalf of themselves and all others similarly situated, Plaintiff, v. ACTELION PHARMACEUTICALS LTD., ACTELION PHARMACEUTICALS US, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, Defendants.	CASE NO. 18-cv-3560-GLR

TRACLEER PURCHASER PLAINTIFFS' FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs, the Mayor and City Council of Baltimore and Government Employees Health Association, Inc. (collectively, "Plaintiffs" or the "purchasers"), bring this action on behalf of themselves and all others similarly situated against Actelion Pharmaceuticals Ltd.; Actelion Pharmaceuticals US, Inc., and Janssen Research & Development, LLC (collectively, "Defendants" or "Actelion"). These allegations are based on publicly available materials and on Plaintiffs' knowledge, information, and belief.

I. INTRODUCTION

1. In May 2018, then-Food and Drug Administration (FDA) Commissioner Dr. Scott Gottlieb issued a public statement aimed at "reducing the ability of brand drug makers to use REMS [Risk Evaluation and Mitigation Strategy] programs as a way to block timely generic drug entry."[1] Dr. Gottlieb explained that the U.S. system for developing new drugs is based on "a careful equilibrium enshrined in legislation by Congress" that balances market-based rewards for medical innovation, on the one hand, against promotion of "brisk competition from safe and effective generic medicines" after patent protection expires, on the other, he pointed to "tactics that brand drug makers adopt" as the reason that such competition sometimes fails. Dr. Gottlieb observed:

> One such abuse that I've spoken about often is a practice by brand companies to create obstacles for generic developers in purchasing samples of their brand drugs. In general, generic drug developers need the samples of the brand drug to develop their generic product and/or to conduct testing to show that their product is bioequivalent to the brand drug for FDA approval. A generic drug developer generally needs 1,500 to 5,000 units of the brand drug to perform what are often relatively straightforward studies for FDA approval. Without these samples, generic drug makers may not be able to develop generic alternatives. Yet, the FDA has heard that some

[1] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new policies to reduce the ability of brand drug makers to use REMS programs as a way to block timely generic drug entry, helping promote competition and access*, U.S. FOOD & DRUG ADMIN. (May 31, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policies-reduce-ability-brand-drug-makers-use-rems.

> brand companies will adopt tactics to make it hard for the generic companies to purchase these brand drugs at a fair value and in the open marketplace.

2. Following Dr. Gottlieb's statement, the first step that the FDA took to address brand companies' "exploitation" of REMS was to publish a list of companies that were "blocking access to the samples of their branded products" and the corresponding total number of complaints it received as to each drug product. Of the 52 drug products on the FDA's published list, Actelion was the manufacturer of four: Opsumit (eight complaints), Tracleer (14 complaints), Veletri (one complaint), and Zavesca (one complaint). There are more than 500 unique companies selling branded drugs in the United States. One company, Actelion, accounted for almost eight percent of the total drug products that exploited REMS to block access to samples. And its Tracleer product drew the highest number of complaints of all the products included on the FDA's list.

3. "Tracleer" is Actelion's brand name for bosentan, a dual endothelin receptor antagonist that treats pulmonary artery hypertension ("PAH"), a chronic, progressive, and potentially fatal disorder affecting between 10,000 and 20,000 people in the U.S.[2] PAH treatment is expensive, costing over $100,000 per patient per year on average. Tracleer is also a highly profitable drug that has earned billions for Actelion.

4. In this case, purchasers of Tracleer seek to hold Actelion accountable for its anticompetitive scheme to prolong its bosentan monopoly using the pretext of a REMS program, forcing purchasers to pay higher prices for bosentan for far longer than they otherwise would have.

5. Actelion's last legal exclusivity over the use of bosentan as a PAH treatment expired in November 2015. While would-be competitors began working on a generic as early as

[2] In PAH patients, elevated blood pressure in the arteries of the lungs causes narrowing of the arteries from the heart to the lungs, restricting blood flow and causing strain on the heart. Without treatment, only about 70% of PAH patients survive a year after diagnosis.

2009, Actelion's scheme blocked or delayed them from even filing an application for approval by the FDA. As a result, generic competition was delayed. No competitor brought a generic version to market until April 2019.

6. Actelion's scheme worked as follows. When it approved bosentan in 2001, the FDA required Actelion to implement a REMS program to alert prescribers, pharmacists, and patients to the risks associated with Tracleer (liver damage, birth defects), and to track patients' usage of the drug. Facing the threat of generic competition years later, Actelion used the pretext of the REMS to refuse would-be competitors' requests for access to samples of the branded product. Without such samples, a generic manufacturer cannot run the laboratory tests necessary to demonstrate bioequivalence, cannot begin the process of seeking regulatory approval, and is effectively blocked from bringing a competing generic product to market.

7. While it pointed to its Tracleer REMS as its reason for withholding samples, Actelion also insisted, falsely, that it had an unrestrained right to pick and choose with whom it does business and simply chose not to sell to prospective competitors. Actelion also falsely claimed that, under its REMS, it is only allowed to sell Tracleer to its shortlist of certified wholesalers.

8. The FDA repeatedly told Actelion that its REMS did not bar sales of samples to would-be competitors. Notwithstanding its REMS, Actelion did make Tracleer available to non-wholesalers, such as researchers – who were not its competitors – when doing so suited its own needs.

9. Actelion blocked and delayed generic companies' access to samples for one reason: to prolong its monopoly well past its legitimate period of market exclusivity.

10. Actelion's anticompetitive scheme was effective. For more than three years after the expiration of the Tracleer patent, no generic Tracleer was available in the United States.

Meanwhile Actelion continued to occupy 100% of the bosentan market and sell Tracleer to Plaintiffs and other purchasers at supra-competitive prices.

11. Despite the relative rarity of PAH and the requirements of Actelion's REMS, Tracleer was a hugely successful product for Actelion, accounting for a large majority of the company's revenues. By the end of 2009, global sales of Tracleer were just short of $1.4 billion a year, and Tracleer was being sold commercially in 58 countries worldwide.

12. Without Actelion's illegal conduct, at least one generic version of Tracleer would have been available in the U.S. at or around the expiration of Tracleer's patent protection in November 2015, or in any event, earlier than April 2019. Defendants' unlawful conduct delayed generic versions of Tracleer from entering the market, blocked competition, and cost purchasers hundreds of millions of dollars in overcharge damages.

II. JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; there are more than one hundred members of the class; and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

14. In the alternative, the Court has jurisdiction over this action pursuant to Section 2 of the Sherman Act and Sections 4 and 16 of the Clayton Act because Plaintiffs request injunctive and equitable relief and seek to recover overcharges and treble damages for injuries sustained by Plaintiffs and the class resulting from Defendants' unlawful foreclosure of the United States market for bosentan. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

15. Defendants transact business within this District and/or have agents in and/or that can be found in this District. Venue is appropriate in this District under Section 12 of the Clayton Act[3] and under 28 U.S.C. § 1391(b) and (c).

16. The Court has personal jurisdiction over each of Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District.

III. THE PARTIES

17. Plaintiff, the Mayor and City Council of Baltimore ("City of Baltimore"), is a municipality located in Baltimore, Maryland. During the Class Period, as defined below, the City of Baltimore purchased, paid, and/or provided reimbursement for some or all of the purchase price of Tracleer in Maryland. The City of Baltimore paid more than it would have for bosentan absent Defendants' unlawful anticompetitive scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Absent the unlawful conduct alleged herein, the City of Baltimore would have purchased less expensive generic alternatives rather than branded Tracleer.

18. Plaintiff, the Government Employees Health Association ("GEHA"), is a not-for-profit corporation providing health and dental plans to federal employees and retirees and their families through the Federal Employees Health Benefits Plan and the Federal Employees Dental and Vision Insurance Program. GEHA is the second-largest national health plan and the second-largest national dental plan serving federal employees, federal retirees, and their families,

[3] 15 U.S.C. § 22.

providing benefits to nearly 1.5 million covered lives with federal employee members residing in all 50 states as well as the District of Columbia and Puerto Rico. GEHA is organized under the laws of Missouri and its principal place of business is located at 310 NE Mulberry Street, Lees Summit, Missouri 64086-5861. During the Class Period, as defined below, GEHA purchased, paid, and/or provided reimbursement for some or all of the purchase price of Tracleer in California, Colorado, Florida, Louisiana, Pennsylvania, Ohio, Kansas, Tennessee, and Texas. GEHA paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent and delay generic entry and was injured as a result of the wrongful conduct alleged herein. Absent the unlawful conduct alleged herein, GEHA would have purchased less expensive generic alternatives rather than branded Tracleer.

19. Defendant Actelion Pharmaceuticals Ltd. is a Swiss corporation having its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

20. Defendant Actelion Pharmaceuticals US, Inc. is a Delaware corporation having its principal place of business at 5000 Shoreline Court, Suite 200, South San Francisco, California 94080. Actelion Pharmaceuticals US, Inc. is a subsidiary of Defendant Actelion Pharmaceuticals Ltd.

21. Defendant Janssen Research & Development, LLC, is a New Jersey corporation having its principal place of business at 920 U.S. Highway 202, Raritan, NJ 08869. Actelion Clinical Research Inc. was merged into and with Defendant Janssen Research & Development, LLC on January 1, 2019.[4] Defendants Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals

[4] Actelion has stipulated, and the Court has recognized, that "the proper corporate party with respect to named party Actelion Clinical Research Inc. is, in fact, Janssen Research & Development, LLC, a wholly-owned subsidiary of Janssen Biotech, Inc., a wholly owned subsidiary of Johnson and Johnson." ECF Nos. 38, 42.

US, Inc., and Janssen Research & Development, LLC are all wholly owned subsidiaries of Johnson & Johnson.[5]

22. All three defendant entities are referred to individually and collectively herein as "Actelion."

23. Defendants' wrongful actions described in this complaint are part of, and were taken in furtherance of, the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

IV. ECONOMIC BACKGROUND

24. The marketplace for the sale of prescription pharmaceutical products in the United States is unusual. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

25. The pharmaceutical marketplace, in contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the product selection and the payment obligation. The patient (or his or her insurer) has the

[5] ECF Nos. 40, 41, 43.

obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

26. In 1984, Congress sought to ameliorate this "disconnect" by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed further below. Now, when a pharmacist receives a prescription for a branded drug and an AB-rated[6] generic version of that drug is available, state laws permit (and in many cases require) the pharmacist to dispense the generic instead of the brand. In this way, price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is lessened. When generic competition is not prevented, and an AB-rated generic equivalent is introduced, brand manufacturers can no longer exploit the "disconnect," their monopoly power dissipates, and some of the normal competitive pressures are restored. Because AB-rated generic versions of branded products are commodities that cannot otherwise be differentiated, the primary basis for generic competition is price.

27. Until the generic version of a brand drug enters the market, however, there is no bioequivalent generic to substitute for and compete with the branded drug, so the brand manufacturer can continue to profitably charge supra-competitive prices.

28. Brand drug manufacturers, well aware of the rapid erosion of brand drug sales by generics, have a strong incentive to delay the start of generic drug competition.

29. Brand manufacturers like Actelion are thus highly motivated to delay generics' entry into the market, thereby extending the brands' monopolies for as long as possible.

[6] AB-rated generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic.

30. Typically, generics are at least 25% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% less expensive when there are multiple generic competitors on the market for a given brand (and can be even more discounted). Consequently, the launch of one or more bioequivalent generic drugs usually results in significant cost savings to all drug purchasers. Generic competition enables all members of the proposed class to purchase generic versions of the drug at substantially lower prices and to purchase the brand drug at a reduced price.

31. The combination of these factors—the regulatory interchangeability of bioequivalent generics for the brand, state substitution laws, margin incentives of pharmacies, and the like—results in the typical phenomenon that once a brand drug "goes generic," the product swiftly moves from a monopoly priced to a commodity priced item.

32. The Hatch-Waxman Act has significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for brand drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2019 it was around $500 billion.[7]

33. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, brand drug manufacturers view competition from generics as a grave threat to their bottom lines.

[7] Tichy EM, et al., *National trends in prescription drug expenditures and projections for 2020*, 77 Am J Health Syst Pharm. 1213 (July 23, 2020).

34. When a brand drug faces generic drug competition, purchasers are able to purchase generic versions of the drug at much lower prices and/or purchase the brand drug at a reduced price.

V. REGULATORY BACKGROUND

A. A New Drug Application must show that the brand drug is safe and effective.

35. Under the Federal Food, Drug, and Cosmetics Act ("FDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments"), drug companies who wish to sell a *new* drug product must file a New Drug Application ("NDA") with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug, including information from at least two clinical trials.

36. An NDA applicant must submit to the FDA information about each patent that purportedly covers the drug product or methods of using the drug product described in an NDA and for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[8] The FDA then publishes this information in a digest titled *Approved Drug Products with Therapeutic Equivalence Ratings* (known as "the Orange Book").

37. Once a brand manufacturer lists a patent in the Orange Book, that listing puts potential generic competitors on notice that the brand company considers the patent to cover its drug. The listing triggers important regulatory consequences.

[8] 21 U.S.C. § 355(b)(1), (c)(2).

B. An Abbreviated New Drug Application must show that the generic is pharmaceutically equivalent and bioequivalent to the brand.

38. One of the primary ways that the FDA facilitates a competitive marketplace is through the efficient approval of generic drugs. Generics cost less than brand drugs. Although generic drugs account for 80% of prescriptions filled in the United States, they comprise only about 27% of overall prescription drug costs.

39. Congress passed the Hatch-Waxman Amendments to the FDAC to balance the need to provide brand companies with incentives to develop new medicines against the countervailing need to speed the entry of cheaper, equally effective generic versions of these medications. According to the FDA, "[i]n passing the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Congress created a system that balances encouraging and rewarding medical innovation with facilitating robust and timely market competition."[9]

40. The Hatch-Waxman Amendments were designed to ensure the timely introduction of generic drugs in the market. To speed the introduction of low-cost generic drugs to market, the amendments enable generic manufacturers to file ANDAs with the FDA. Rather than requiring generic manufacturers to conduct expensive clinical trials to re-prove the drugs' safety and efficacy, Congress chose to allow generic manufacturers to rely on the data that the brands have already submitted to the FDA to prove the drugs' safety and efficacy. Instead of conducting their own clinical trials, generic manufacturers must show that their generic versions are both pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the already-approved brand drug (referred to as the "reference listed drug" or "RLD"). The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug

[9] *Reference Listed Drug (RLD) Access Inquiries*, U.S. FOOD & DRUG ADMIN. (Feb 7, 2019), https://web.archive.org/web/20190517175859/http://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries (hereinafter "*RLD Access Inquiries*").

products containing the same active pharmaceutical ingredient, in the same dose, delivered the same way and at the same speed, are equally safe and effective.

41. To obtain FDA approval to sell a generic version of an RLD in the U.S., an applicant must show that the drug product described in the ANDA contains the same active ingredient, same conditions of use, same route of administration, same dosage form, same strength, and same (with certain permissible differences) labeling, and must show that the same amount of the drug gets into the bloodstream over the same time period as the brand drug.

1. Congress gave the FDA broad discretion to evaluate bioequivalence.

42. The FDCA states that a generic drug is "bioequivalent" to the RLD if "the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses."[10]

43. Bioequivalence testing determines whether differences in formulation (*e.g.*, differences in inactive ingredients) between a proposed generic drug and the reference-listed drug have an impact on the rate and extent to which the active ingredient becomes available at the site of action. The statute, regulations, and case law give the FDA considerable flexibility in determining how the bioequivalence requirement may be met. The testing methods may include *in vivo* data (data from a study on live subjects), *in vitro* data (data from laboratory studies), or both. The selection of the method used to meet an *in vivo* or *in vitro* testing requirement depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Applicants are required to conduct bioavailability and bioequivalence testing using the most accurate, sensitive, and reproducible approach available. The method used must be capable of

[10] 21 U.S.C. § 355(j)(8)(B)(i); *see also* 21 C.F.R. § 320.23(b).

measuring bioavailability or establishing bioequivalence, as appropriate, for the product being tested.

44. For systemically acting drug products (like most ordinary pills), the rate and extent of systemic absorption of the drug is usually the most sensitive, accurate, and reliable indicator of the rate and extent to which the active ingredient becomes available at the site of drug action. The determination of the bioequivalence of a drug product whose primary mechanism of action depends on systemic absorption generally rests on a comparison of the drug and/or metabolite concentrations in an accessible biological fluid, such as blood or urine, after administration of a single dose or multiple doses of the drug product to healthy volunteers.

2. Samples are essential for generic companies to establish bioequivalence and thus to obtain ANDA approval.

45. A company seeking to show the FDA that its proposed generic drug is bioequivalent to the RLD must have access to samples of that RLD. Without samples, it is virtually impossible to complete and file an ANDA application for a systemically acting product.

46. FDA regulations require ANDA applications to include "[a] complete study report . . . for the bioequivalence study upon which the applicant relies for approval."[11]

47. The regulations giving guidelines on the design of bioequivalence and bioavailability studies all refer to a comparison of the drug product to be tested and "the appropriate reference material," *i.e.*, the RLD.[12]

48. The FDA has explained why samples are so important:

> **Why are samples of the RLD important to a prospective ANDA applicant?**
>
> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is

[11] 21 C.F.R. § 320.21(b)(1).
[12] 21 C.F.R. § 320.25–320.27.

> bioequivalent to the RLD [*i.e.*, the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[13]

49. Only samples of the RLD approved by the FDA and marketed in the United States ("U.S. samples") may be used for bioequivalence testing purposes.

50. In the ordinary course, an ANDA applicant obtains samples by buying them, at the market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from brand and generic manufacturers for the purposes of re-selling them to pharmacies or other wholesalers.

3. Other features of the generic drug approval pathway.

51. *Patent information/certification.* An ANDA must include one of the following four certifications with respect to the patents covering the branded drug it seeks to produce:

i. That such information has not been filed (a "Paragraph I certification");

ii. That such patent has expired (a "Paragraph II certification");

iii. The date on which such patent will expire (a "Paragraph III certification"); or

iv. That such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (a "Paragraph IV certification").[14]

52. *Conducting bioequivalence testing does not constitute infringement.* The Hatch-Waxman Amendments also made clear that conducting bioequivalence testing with another manufacturer's patented drug product does not infringe that product's patents.

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[13] *RLD Access Inquiries, supra* note 9.

[14] 21 C.F.R. 355(j)(2)(A)(vii)(I)-(IV).

53. *505(b)(2) applications are not ANDAs.* Under certain circumstances, a manufacturer may use a different abbreviated approval pathway in order to receive approval to sell a drug, namely, a 505(b)(2)[15] application.

54. A 505(b)(2) application, like a typical NDA, must contain full reports of the drug maker's investigations into the safety and effectiveness of the drug product it describes. Unlike a typical NDA, however, the application confirms that "one or more of the investigations relied upon by the applicant for approval 'were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.'"[16]

55. A 505(b)(2) application is usually used for changes to a previously approved drug product, such as a change in dosage form, strength, and/or route of administration from a previously approved product.

56. A 505(b)(2) application cannot be used to obtain approval for a duplicate of an approved product and/or a product that is eligible for approval through the ANDA pathway. The FDA has stated that it will generally "refuse to file a 505(b)(2) application for a drug that is a duplicate of a listed drug and eligible for approval under section 505(j) of the FD&C Act."[17]

57. A drug approved pursuant to a Section 505(b)(2) application will not necessarily be rated therapeutically equivalent to the listed drug it references upon approval (and so could not

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[15] 21 U.S.C. § 355(b)(2).

[16] Center for Drug Evaluation and Research (CDER), *Draft Guidance for Industry: Applications Covered by Section 505(b)(2)*, U.S. FOOD AND DRUG AMIN. at 2, 11 (October 1999), https://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf (quoting 21 U.S.C. § 355(b)(2)).

[17] Center for Drug Evaluation and Research (CDER), *Determining Whether to Submit an ANDA or a 505(b)(2) Application*, U.S. FOOD AND DRUG ADMIN. (May 2010), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf.

be automatically substituted for the brand at the pharmacy). Even so, a manufacturer submitting a 505(b)(2) application will, in most cases, need to conduct bioequivalence testing to compare the proposed drug and the reference listed drug.

C. The FDA sometimes imposes REMS.

58. Since at least the 1960s, the FDA has been experimenting with different ways to manage risks related to pharmaceutical products. These efforts began with disclosure requirements, mandating that manufacturers provide complete information about a drug's indications, side effects, and dosing, among other information, to healthcare professionals. The Controlled Substances Act of 1970[18] added regulations governing manufacturers, prescribers, dispensers, and labelers, allowing the FDA to require, *inter alia*, boxed warning messages on packaging and "Dear Healthcare Provider" letters from drug makers.

59. In the 1990s, the FDA began working together with drug manufacturers to develop risk management programs for drugs' potentially dangerous side effects.

60. In the mid-2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), a voluntary system by which drug sponsors implemented risk minimizing plans to address known safety risks.[19]

61. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[20] Section 505-1(a)(1) of the FDAAA authorizes the FDA to require sponsors of drug applications to submit a proposed REMS program if the agency determines that such is needed to ensure that a drug's benefits outweigh its safety risks. A REMS can include a medication guide

[18] 21 U.S.C. 801 *et seq*. (2002).

[19] Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Development and Use of Risk Minimization Action Plans*, U.S. FOOD AND DRUG ADMIN. (March 2005), https://www.fda.gov/media/71268/download.

[20] Pub. L. No. 110-85, 121 Stat. 823.

for patients, a plan for communicating with health care providers about risks, and/or restrictions on the distribution of the drug (such as requiring doctors or pharmacies to obtain special certifications before dispensing the drug; or using some means to monitor the risks to patients, such as a patient registry or requiring periodic medical tests of patients to see whether they are experiencing a dangerous side effect). As examples, the FDA notes that if a drug carries a risk of serious infection, a REMS action might be to require patient education about the initial warning signs of infection prior to prescribing; if a drug is known to bear a risk of liver damage, a REMS might require liver function monitoring while the patient is taking the drug; for drugs that can cause a severe allergic reaction, a REMS might require that only a certified healthcare professional can administer the product; for drugs that can cause severe birth defects, a REMS could require a negative pregnancy test before each prescription can be dispensed.[21]

62. The FDA can require a REMS before a drug enters the market, based on known risks, or after a drug has been approved, based on new evidence of risk. In determining whether a REMS will be required for a particular drug, the FDA considers factors including (1) the size of the population likely to use the drug; (2) the seriousness of the disease; (3) the drug's expected benefit; (4) the expected duration of treatment; (5) the seriousness of adverse effects; and (6) the drug's novelty.[22]

63. Some REMS programs include specific "Elements To Assure Safe Use" (ETASU), which are designed to "provid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable," including requiring the drug's sponsor to monitor and evaluate

[21] *A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)*, U.S. FOOD AND DRUG ADMIN. (July 26, 2018), https://wayback.archive-it.org/7993/20180726111026/https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

[22] 21 U.S.C. § 355-1(a)(1).

the implementation of the ETASU. ETASU may require, *e.g.*, that prescribers have particular training, that entities that dispense the drug be "specially certified," that patients be enrolled in a registry or subject to certain monitoring, or that the drug be dispensed or administered only under certain conditions (in a hospital, or after a negative pregnancy test, for example).[23]

64. ETASUs are *not* intended to make drugs less available or to unduly burden patients, healthcare professionals, or the healthcare system. The FDA specifies that ETASU requirements must be commensurate with the specific serious risk listed in the drug's labeling.[24] Access to the necessary trainings or certifications must be made available for "any willing provider"[25] in some areas.

65. In practical effect, ETASU requirements can restrict a drug's distribution and how it may be sold to consumers. For example, not all prescribers or distributors may want to take on the responsibility of complying with ongoing certification or reporting requirements. The statute, however, does *not* contemplate that ETASU may require that the drug be distributed by only a handful of entities, that the drug be distributed or sold only to patients, or that the brand company be empowered to dictate to whom distributors may re-sell the drug. Rather, it lists steps for training, certification, or monitoring of health care providers, pharmacies, health care settings, or patients.[26]

66. ETASU measures are "designed to be compatible with established distribution, procurement, and dispensing systems for drugs."[27] The FDA has sought to ensure that ETASU

[23] 21 U.S.C. § 355-1(f) and (f)(3).
[24] 21 U.S.C. § 355-1(f)(2).
[25] 21 U.S.C. § 355 1(f)(3)(A) and (B).
[26] 21 U.S.C. § 355-1(f)(3).
[27] 21 U.S.C. § 355 1(f)(2)(C)(ii).

requirements do not burden patients who "have difficulty accessing health care (such as patients in rural or medically underserved areas)" or those with "serious or life-threatening diseases or conditions."[28]

67. Since their enactment in 2007, REMS—and, in particular, ETASU requirements—have been increasingly common in the FDA approval process. Roughly 40% of new drugs have REMS programs.[29]

68. Nothing in the REMS statute, the ETASU provision, or elsewhere in the applicable statutes or regulations prohibits the sale of REMS-controlled drugs to qualified generic companies that will use those drugs in controlled, FDA-required bioequivalence testing.[30]

69. Nothing in the REMS statute, the ETASU provision, or elsewhere in the applicable statutes or regulations, gives an NDA holder the right to interfere with a competitor's ability to purchase samples necessary to perform bioequivalence testing.[31]

D. Brand manufacturers can unlawfully abuse REMS programs to delay or block generic competition.

70. Competition from generics can decimate a brand drug company's profits because the presence of generics in the market dramatically lowers prices for drug purchasers. Once available in the market, generics capture most of the brand's market share within the first year.

71. As the FDA has explained: "One of the primary ways that FDA facilitates a competitive marketplace is through the efficient approval of generic drugs, which are often lower cost than brand drugs. Unfortunately, the process established by Congress may not always function

[28] 21 U.S.C. § 355 1(f)(2)(C(i).

[29] Michael A. Carrier, *Sharing, Samples, and Generics: an Antitrust Framework*, 103 Cornell L. Rev. 1, 7 (2017).

[30] 21 U.S.C. § 355-1 and 21 U.S.C. § 355-1(f).

[31] 21 U.S.C. § 355-1 and 21 U.S.C. § 355-1(f).

as intended. At times, certain 'gaming' tactics have been used by brand drug companies to delay generic competition."[32]

72. An increasingly common "gaming" tactic that brand manufacturers use to delay or defeat generic competition is denying or delaying would-be generic competitors' access to the sample quantities of the brand drug they need to conduct bioequivalence testing. As a leading FDA official testified in 2016, brand companies sometimes use REMS programs designed to ensure safety "as an excuse to not give the drug to the generics so they [the generics] can compare it to their drug." She noted that such behavior causes "barriers and delays in getting generics on the market."[33]

73. The FDA has also looked at the issue of why prospective generic applicants encounter roadblocks to obtaining samples of the RLD:

> Often, generic companies are able to obtain RLD samples through normal drug distribution channels, *i.e.*, via wholesalers. Sometimes, however, samples of the RLD are not available through normal distribution channels. A drug may not be available through standard distribution channels because the RLD sponsor limits the distribution of the drug (for example, by selling it through a central or small group of pharmacies) on its own initiative for a variety of business reasons. In other cases, a REMS with elements to assure safe use (ETASU) might impact the way the product is distributed. For example, only a limited number of pharmacies might be willing and/or able to meet the specific pharmacy certification requirements in a REMS. Once such limitations are in place, we understand that some RLD sponsors (1) refuse to sell the product directly to the generic company (or impose terms on the sale that generic companies find burdensome or impossible to comply with), or (2)

[32] *RLD Access Inquiries, supra* note 9.

[33] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

> place limitations on the ability of pharmacies or wholesalers to sell samples to the generic companies for development purposes.[34]

74. Thus, some brand companies resort to a REMS's restricted distribution provisions as a pretext for refusing to sell (and/or prohibiting their distributors from selling) samples of their drugs to would-be generic competitors. The FDA has recognized the "game."

75. Indeed, Congress anticipated that brand drug manufacturers might improperly try to maintain monopoly profits in this way. When it enacted the FDAAA, it thus included Section 505-1(f)(8), which explicitly prohibits brand drug manufacturers from using a REMS ETASU "to block or delay approval of" an ANDA, in the statute.

76. The FDA has noted that when brand companies wrongfully use REMS or other limited distribution programs "as a basis for blocking potential generic applicants from accessing the samples [of the RLD]," the generic drug development process "slows down[] or [is] "entirely impede[d] . . . leading to delays in bringing affordable generic alternatives to patients in need."[35]

77. Such conduct undermines the competition between brands and generics that is at the heart of the Hatch-Waxman Act. A brand drug maker's strategic refusal to sell samples to generics also flouts the statute's direct prohibition on using a REMS program to block or delay ANDAs by preventing would-be generic competitors from accessing samples of drugs.

78. When brand manufacturers play this game, generic companies have no recourse. A generic manufacturer cannot buy the drug from its normal suppliers, because the brand company is refusing to allow the distributor to sell to the generic (often citing the REMS ETASU restrictions). It cannot use foreign (*i.e.*, non-U.S.) samples as substitutes because the FDA does not consider a foreign sample to be the same drug product for bioequivalence testing purposes. It

[34] *RLD Access Inquiries*, *supra* note 9.
[35] *Id.*

cannot file a 505(b)(2) application because (1) the FDA says that 505(b)(2) applications are not the right vehicle for seeking approval of a substitutable generic drug *and* (2) submitting a 505(b)(2) application would still require testing samples. Even if a generic knows the exact "recipe" of a brand formulation, it cannot manufacture its own version for testing purposes because only the brand's product constitutes the "reference listed drug" to which the ANDA product must be compared.

E. Congress and the FDA have tried to prevent brand companies from using REMS to block or delay generics.

79. By all accounts, the problem of REMS abuse is growing. One study of 40 drugs subject to restricted access REMS programs found that generics' resulting inability to enter the market increases U.S. healthcare costs by more than $5 billion a year.

80. In recent years, members of Congress from both sides of the aisle have spoken out against the practice of using REMS to block generic firms' access to drug samples. Senator Charles Grassley (R-IA) strongly criticized brand firms that "misus[e] their . . . REMS[] to withhold access to drug samples for bioequivalence testing and generic drug development in violation . . . of FDA regulations and the Hatch-Waxman Act."[36] Likewise, Senator Patrick Leahy (D-VT) lamented that "[t]his simple delay tactic uses regulatory safeguards as a weapon to block competition."[37] A 2016 Senate report lamented that brands need not even refuse to deal with a generic to effectively stifle

[36] Prepared Statement by Senator Chuck Grassley of Iowa Chairman, Senate Judiciary Committee Antitrust Subcommittee Hearing on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition" (June 21, 2016), https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Grassley%20Statement.pdf.

[37] 162 Cong. Rec 94 (2016) (statement of Sen. Patrick Leahy (D-VT)).

competition; instead they "simply engage in never-ending negotiations that have the effect of delaying entry." [38]

81. Courts, too, have noted that brand drug companies sometimes find ways to manipulate REMS programs to preclude a generic from filing an ANDA, and that doing so may violate the antitrust laws.

82. REMS abuse has become rampant. In an effort to facilitate access to samples of branded drugs, the FDA began issuing "safety determination" letters to brand companies that confirmed, in writing, that the FDA would not consider providing samples of the RLD for these purposes to be a violation of the REMS. In 2014, the FDA stated,

> In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE [bioequivalence] study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.[39]

83. The FDA's safety determination letters inform the brand manufacturer that:

- The FDA has received a request from a prospective generic applicant seeking help in obtaining samples of the brand product for purposes of testing the proposed generic against the brand/reference listed drug;

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[38] S. Special Comm. on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* 114th Cong., 2, 115 (2016).

[39] Center for Drug Evaluation and Research (CDER), *Draft Guidance on How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD*, U.S. FOOD AND DRUG ADMIN., at 2 (December 2014) https://wayback.archive-it.org/7993/20190207215240/https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf (hereinafter "CDER Draft Guidance").

- The brand drug has a REMS in place;
- The generic's proposed study protocols include safety precautions comparable to those set forth in the brands' REMS;
- The FDA *will not consider it a violation of REMS* for the brand to provide the prospective generic applicant a quantity of the brand product sufficient to support its ANDA;
- The FDCA prohibits NDA holders from using elements of a REMS to block or delay approval of a generic product;
- The NDA holder should supply the generic with a sufficient quantity of the RLD to enable it to conduct the testing necessary;
- Holders of NDAs covered by a REMS are prohibited by law from using any ETASU to block or delay approval of an ANDA.[40]

84. Despite the FDA's efforts to help generics by issuing such letters, the FDA has made it very clear that there is no requirement that a generic company seek or obtain such a letter from the FDA in order to obtain samples of an RLD: "Requesting or obtaining such a letter from FDA is not a legal requirement."[41]

85. In 2016, a Senate committee concluded that the FDA has "attempted to stymie [brands'] obstruction" by providing letters to generic companies indicating that the agency "see[s] no safety risk," but that the agency's "actions have been largely ineffective."[42]

86. In 2017, the FDA took the further step of committing to responding to inquiries from generics seeking help accessing samples within 60 days of receipt.

87. On May 17, 2018, the FDA announced that it would begin regularly publishing a list of drugs that have been the target of complaints that their NDA holders are denying access to

[40] FDA's Sample Safety Determination Letter, https://www.fda.gov/media/111808/download.
[41] CDER Draft Guidance, *supra* note 39, at 2.
[42] S. Special Comm. on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* 114th Cong., 115 (2016).

samples to generic companies that seek to buy them.[43] The initial list confirmed that the FDA had sent at least 21 safety determinations letters to at least six brand companies. Its larger list specified 57 different drugs, with annual combined sales of $13.9 billion, to which sample access had reportedly been denied. The names of the prospective generic applicant companies who sought and received these letters are not made publicly available.

88. The FDA's February 7, 2019 list reported complaints concerning four different Actelion products as to which inquiries about impeded access had been received: Opsumit (eight complaints), Tracleer (14 complaints), Veletri (one complaint), and Zavesca (three complaints).[44]

89. To date, the FDA has issued five Safety Determination Letters to Actelion concerning access to sample quantities of Tracleer. The first of the five Safety Determination Letters to Actelion about Tracleer samples was dated July 31, 2013; two were dated September 1, 2015; another was dated October 16, 2015, and one was dated January 29, 2016.[45] These letters inform Actelion that it may provide samples of Tracleer to five different generic manufacturers without violating Actelion's REMS. In each of the letters, the FDA advised that it had reviewed the specific protocols that the particular generic company proposed to use in its clinical trials of Tracleer and the generic product, and that the proposed protocols were adequate to protect the safety of test subjects.

[43] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition* (May 17, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-efforts-shine-light-situations-where-drug

[44] *RLD Access Inquiries*, *supra* note 9. Like Tracleer, Opsumit is a PAH medicine subject to a REMS with an ETASU. *See* http://www.opsumit.com; http://www.opsumitrems.com.

[45] *RLD Access Inquiries*, *supra* note 9.

VI. FACTS

A. 1990–2001: Tracleer (bosentan) is developed, approved, and launched.

1. Scientists at Hoffman-LaRoche discover and patent bosentan.

90. In the 1990s, researchers at Hoffman-LaRoche Inc. ("Roche") discovered and developed the endothelin receptor antagonist bosentan.

91. In 1992, seven Roche-based co-inventors of the bosentan molecule submitted U.S. Patent Application No. 896,015.

92. On March 8, 1994, the United States Patent and Trademark Office ("PTO") issued the resulting patent, U.S. Patent No. 5,292,740 ("the '740 patent"). It was assigned to Roche. The '740 patent was listed as covering Tracleer in the FDA's Orange Book from 2001 until the patent expired on November 20, 2015.

93. The '740 patent discloses that the claimed compounds (ostensibly including bosentan) can be used to treat disorders "associated with endothelin activities," including hypertension and pulmonary high blood pressure.

94. The '740 patent would and did expire on November 20, 2015.

2. Actelion Pharmaceuticals, a Roche spin off, obtains an exclusive license for the bosentan patent.

95. In 1997, a small group of scientists and managers, including two of the '740 patent's inventors, left Roche to found Actelion Pharmaceuticals Ltd. From 1997 on, Actelion Pharmaceuticals Ltd. has been the exclusive licensee to the '740 patent. Roche gave Actelion (and only Actelion) the right to develop, make, and sell products covered by the '740 patent—including products containing the compound bosentan.

3. The FDA reviews and approves Actelion's Tracleer.

96. On November 17, 2000, Actelion filed an NDA seeking FDA approval to sell tablets containing bosentan, bearing the tradename Tracleer.

97. Actelion asked the FDA to approve the drug to treat PAH. Pulmonary hypertension refers to abnormally high blood pressure in the blood vessels connecting the lungs and the heart. PAH—a subset of pulmonary hypertension—occurs when the small arteries in the lungs narrow or become scarred. This restricts blood flow, increases blood pressure, and reduces the amount of oxygen in the blood. Over time, PAH causes damage to the heart as well as the lungs.

98. Risk factors for PAH include a family history, obesity, sleep apnea, gender, pregnancy, altitude, various diseases (including heart disease, lung disease, liver disease, HIV, COPD, and lupus), and methamphetamine or cocaine use. The most common window of diagnosis is between 20 and 60 years of age. Idiopathic PAH (*i.e.*, PAH that arises spontaneously or for which the cause is unknown) is twice as common in women as in men. Women of childbearing age are thought to be more susceptible.

99. At the time Actelion filed its NDA, there were no approved oral products available to treat PAH.

100. Actelion's NDA included two double-blind randomized clinical studies intended to support the oral formulation's efficacy. Actelion also submitted an open label (*i.e.*, not double-blind) safety study.

101. The FDA's review of Actelion's studies identified serious hepatotoxicity (liver problems) and teratogenicity (the potential to cause birth defects), as well as other potential side effects.

102. The FDA observed that about 10-11% of patients who took bosentan during the clinical trials experienced increased liver-produced enzymes in the blood that were at least three

times the upper limit of normal; one patient had an elevated liver-enzyme level that was 73 times higher than his baseline value. The FDA noted that there was no indication that bosentan was tied to any death, that there were no reports of liver failure or need for liver transplant, and that there was no indication that the increase in liver enzymes was not reversible by discontinuing the drug (and, in fact, liver effects appeared reversible). The FDA recommended that, because of the toxic effects on the liver, both a patient registry and specific education for physicians who treat patients with PAH be implemented prior to the marketing of Tracleer.

103. The FDA concluded that bosentan was teratogenic (*i.e.*, capable of causing congenital anomalies or birth defects) and fetotoxic (*i.e.*, capable of poisoning or causing degenerative effect in a developing fetus or embryo) in rats. Observed defects in fetuses included craniofacial abnormalities and blood vessel variations. These effects were not observed in rabbits.

104. The FDA's pharmacology review ultimately recommended that Tracleer be approved — despite toxicity concerns — "because of the seriousness of the proposed indication [PAH] and the lack of alternative oral therapy."[46]

105. On November 20, 2001, the FDA approved Tracleer to treat PAH. Tracleer became Actelion's first and flagship product. In the FDA's letter approving the Tracleer NDA, the agency notified Actelion that, "based on information from pre-marketing studies, FDA has determined that Tracleer (bosentan) poses a serious and significant public health concern," namely risks of liver toxicity and of birth defects if the drug was taken by pregnant patients.[47]

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[46] Tracleer (Bosentan) Tablets Drug Approval Package, Pharmacology Review, Part 3, p. 33 of 62. (November 2001), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-290_Tracleer_pharmr_P3.pdf.

[47] Center for Drug Evaluation and Research Tracleer (Bosentan) Tablets Drug Approval Package, Application Number 21-290 (November 20, 2001), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-290_Tracleer_Approv.pdf.

106. The FDA granted Tracleer two regulatory exclusivities. Because it was a new chemical entity, Tracleer was entitled to five years of regulatory exclusivity (expiring on November 20, 2006). Tracleer was also given status as an "orphan drug," thus providing an additional two years of market exclusivity. These regulatory exclusivities—lawful forms of monopoly—guaranteed that Tracleer would not face competition from generics until November 2008 at the earliest.

107. Actelion also submitted the '740 patent for listing in the FDA's Orange Book as covering Tracleer. The '740 patent expired on November 20, 2015.

B. 2001–2006: Actelion initially distributes Tracleer through the Tracleer Access Program (TAP)'s restricted distribution network.

108. In approving the NDA, the FDA told Actelion that a "Tracleer Access Program is an important part of the post-marketing risk management for Tracleer," and specified eight component parts of that prescribed program, including ". . . (3) Distribution of Tracleer through a restricted distribution network."[48]

109. The Tracleer Access Program (TAP) specified that "TAP triages the prescription to a Specialty Distributor," and that, to be approved to sell Tracleer, each specialty distributor must agree to a defined set of rules, including inserting patient reminders in the patient's prescription package, writing to the prescribing physician providing details regarding the prescription, periodic reminders to patient about the need for liver function tests and pregnancy testing in appropriate cases, and tracking cessations of the prescription including adverse medical events.[49] The TAP makes no reference to Actelion needing to pre-approve, or having veto power over, sales made by the distributor to generic companies or any companies.

[48] *Id.*
[49] *Id.*

C. 2007–2008: After enactment of the REMS statute, the FDA determines that a Risk Evaluation and Mitigation Strategy (REMS) was already in effect for Tracleer.

110. In 2007, six years after Actelion launched Tracleer with the restricted distribution "Tracleer Access Program," Congress passed the FDAAA.[50] Section 901 of the FDAAA created new Section 505-1 of the FDCA, titled "Risk evaluation and mitigation strategies," discussed above at Section V.C. Again, the law included a provision explicitly forbidding NDA holders, such as Actelion, from using elements of REMS to block or delay approval of a generic product.[51] The Amendments went into effect on March 25, 2008.

111. Two days later, on March 27, 2008, the FDA published a notice in the Federal Register addressing the new law. The notice: (1) explained that the FDA had determined that some approved drug products already had an approved REMS program in effect (although the term "REMS" may not have been used to describe the programs before the statute was enacted), and (2) asked those drugs' sponsors to submit a proposed REMS program by September 21, 2008.[52]

112. Tracleer was one of the twenty drugs on the FDA's "already have a REMS" list.

113. On September 19, 2008, Actelion submitted a supplemental NDA including a proposed REMS as requested by the FDA (it was later amended). Actelion's proposed REMS included a Medication Guide, ETASU, and the timetable for submission of assessments. The specifics of this REMS were designed and proposed by Actelion, and the FDA accepted Actelion's proposal.

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[50] Pub. L. No. 110-85, 121 Stat. 823.

[51] 21 U.S.C. §355-1(f)(8).

[52] Center for Drug Evaluation and Research (CDER), *Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications: Guidance for Industry*, U.S. FOOD AND DRUG ADMIN. (October 2017) at 3, https://www.fda.gov/media/77846/download.

114. Actelion's proposed REMS was substantially similar to the "Tracleer Access Program." The goals of Actelion's REMS were:

1. To inform prescribers, patients, and pharmacists about the risks of Tracleer;
2. To minimize the risk of hepatotoxicity in patients who are exposed to Tracleer;
3. To minimize the risk of fetal exposures in female patients who are exposed to Tracleer; and
4. To educate prescribers, patients, and pharmacies on the safe-use conditions for Tracleer.

115. On November 20, 2008, Tracleer's orphan drug exclusivity lapsed. The only remaining exclusivity was from the '740 patent (which would expire on Nov. 20, 2015).

D. 2009: Actelion's newly proposed REMS goes into effect.

116. In approving Actelion's proposed REMS in 2009, the FDA reiterated that it had determined that a REMS was necessary for Tracleer "to ensure the benefits of the drug outweigh the risks of hepatotoxicity and teratogenicity."

117. The FDA identified specific data points to be addressed in Actelion's future REMS assessment plans, including that Actelion should provide "distribution data from the certified pharmacies." The FDA did not suggest that Actelion should refuse to sell samples to generic manufacturers, nor that Actelion should prevent certified pharmacies from distributing Tracleer to generic manufacturers seeking to purchase samples. The FDA simply asked Actelion to report to whom (whether entities or patients) Tracleer was distributed.

118. Actelion's proposed REMS mandated responsibilities for Actelion, physicians and other health care providers, pharmacies, and patients as part of the ETASU.[53]

[53] Actelion, *Risk Evaluation Mitigation Strategy (REMS), Tracleer (bosentan), NDA 21-290* (July 28, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290.pdf (approved, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/021290s016ltr.pdf).

119. Between August 7, 2009 and October 20, 2017, Actelion updated its REMS seven times. At no time did Actelion's REMS ever enable or require it to refuse to sell samples to a generic manufacturer, to prevent its distributors from selling samples to generic companies, or otherwise to obstruct generic applications and approvals.

E. Actelion completely controls the bosentan market.

1. Actelion prevents its distributors from selling to generic companies, sometimes using the pretext of REMS restrictions.

120. Actelion distributes Tracleer through certified distributors/wholesalers. Actelion has entered into contractual agreements with each distributor under which such participants agree with Actelion not to supply Tracleer to any entity without Actelion's approval. Put differently, distributors are precluded from supplying Tracleer to generic companies and others as a condition of doing business with Actelion. Actelion itself has described these as unilateral conditions imposed on distributors. By means of these contractual terms, Actelion controls the certified distributors/wholesalers, who have effectively become agents of Actelion for these purposes. Actelion determines what companies, researchers, or individuals the distributors may sell to. With regard to the wholesalers' refusals to sell samples of Tracleer that are at issue here, the certified distributors/wholesalers have functional unity with Actelion and are within Actelion's functional control.

121. On information and belief, each of Actelion's contracts with the certified distributors/wholesalers bars the certified distributors/ wholesalers from bringing suit against Actelion for violations of federal or state antitrust laws.

122. Actelion closely monitors its distributors' sales of Tracleer.

123. Actelion has acknowledged that its restrictions make it impossible for generic manufacturers to buy samples downstream.

124. While Actelion, at times, has stated that it imposed these restrictions because of its REMS, this is not the case. Neither Congress, the FDA nor Actelion's REMS requires Actelion to impose exclusive distribution agreements that prohibit distributors from selling samples of Tracleer to generic manufacturers for testing purposes. This extreme form of restricted distribution was Actelion's brainchild, intended to prolong its Tracleer monopoly.

2. Actelion provides access to Tracleer samples to researchers.

125. Actelion's representations to would-be generic competitors that it was prohibited from providing samples outside its REMS program were false. Over the past twenty years, including since Actelion's REMS went into effect, Actelion has allowed access to Tracleer samples — directly or indirectly — for at least 32 publicly disclosed clinical studies conducted by entities *other than Actelion.* These studies have been conducted by universities, research hospitals, the National Institute of Health, and large brand-name pharmaceutical companies.

126. Actelion regularly provides samples for use in studies outside of its Tracleer Access or REMS programs. For example, in 2001 Actelion sponsored and provided bosentan for a placebo-controlled study led by researchers at the University of California at San Diego ("UCSD") and conducted in several countries, including the United States. Two hundred and thirteen PAH patients participated in the UCSD study, 114 of whom were given bosentan. Actelion also funded a 2007–2008 University of California San Francisco ("UCSF") study of morbidity and mortality among 616 patients with Idiopathic Pulmonary Fibrosis treated with bosentan over a one-year period. The UCSF study included male patients from around the world, including 185 in the U.S., who were given bosentan. From 2008 to 2012, Actelion provided bosentan for a study sponsored by the University of Cincinnati, which was designed to determine whether bosentan can help patients whose PAH is associated with sarcoidosis, and in which 43 sarcoidosis patients from across the United States were given either bosentan or a placebo twice a day for 16 weeks. From

2010 to 2013, Actelion provided bosentan for a study sponsored by the University of California, Los Angeles ("UCLA"), in which 10 U.S. patients with congenital heart disease were given bosentan twice daily for three months. Actelion's purported safety concerns ring hollow when it provides samples to non-wholesalers such as researchers and research organizations that pose no competitive threat to Actelion's monopoly, while simultaneously refusing to provide access to samples to potential generic competitors.

127. Actelion also provided samples for use in studies that Actelion did not fund or sponsor. For example, Actelion provided bosentan for a long-term study sponsored and led by researchers at Vanderbilt University that was designed to assess the efficacy of bosentan and other anti-hypertension drugs for treating supine hypertension. In the Vanderbilt study, which lasted from 2001 to 2017 and was based in Nashville, Tennessee, researchers gave 152 adult participants a randomly-chosen medication—one of which was bosentan—and measured their blood pressure monitored over a 24-hour period. Beginning in or around September 2006, Actelion also provided bosentan for a study sponsored and led by researchers at Pfizer designed to assess the efficacy and safety of sildenafil, another PAH drug, in combination with bosentan. In the Pfizer study, which lasted from 2006 until 2013, 105 participants in the US and abroad were given bosentan daily for 16 months, along with either sildenafil or a placebo. Beginning in or around August 2011, Actelion provided samples to Novartis for a study designed to measure the effect of imatinib, a cancer treatment, on the pharmacokinetics of bosentan. The Novartis study lasted from 2011 to 2012, and was included 21 participants from around the world, including the United States, who were given bosentan twice daily for 36 days. Actelion has also provided bosentan since in or around June 2015 for an ongoing study sponsored and led by researchers at Augusta University and the National Heart, Lung, and Blood Institute, in which approximately 320 adult men and women in Augusta,

Georgia have been given either bosentan or a placebo in order to measure the effect of bosentan on the bodies' stress response and vascular function. On information and belief, Actelion had no ability to control the use of bosentan in studies it did not fund or sponsor. The fact that Actelion regularly provided samples to researchers over which it had no control demonstrates the falsity of Actelion's assertion that it could not provide samples of bosentan outside of its REMS due to purported safety concerns.

F. 2009–2012: Generics seek access to Tracleer samples to Conduct Bioequivalence Testing.

1. Zydus attempts to buy samples from Actelion.

128. In November 2009, Zydus Pharmaceuticals (USA) Inc. ("Zydus") and its partner, Cadila Healthcare Ltd. ("Cadila") (collectively, "Zydus/Cadila"), sought to purchase U.S. samples of Tracleer from a pharmaceutical wholesaler for the purposes of conducting bioequivalence testing for an anticipated U.S. ANDA. The wholesaler said it could not sell them the U.S. version of Tracleer.

129. In December 2010, Zydus/Cadila again sought to buy U.S. Tracleer samples, this time from a different wholesaler. Again, they were told that the wholesaler could not provide U.S. Tracleer samples.

130. On June 7, 2010, Zydus sent a letter to Actelion requesting to purchase Tracleer samples and offering to pay prices that would have been profitable for Actelion. In its letter, Zydus explained the following with respect to its request for Tracleer samples:

- The samples are "for bioequivalence testing purposes."
- [Zydus] "will pay Actelion Ltd. the wholesale acquisition cost (WAC) of the requested drug product and will reimburse Actelion Ltd. for any shipping costs."
- [Zydus/Cadila] "commit[s] that [their] procedures for conducting bioequivalence testing . . . will fully comply with FDA requirements. Zydus

> Pharmaceuticals (USA) Inc.'s controls with respect to TRACLEER (bosentan) used in bioequivalence testing will be comparable to the T.A.P. - Tracleer Access Program and will comply with the prescribing and dispensing instructions in the approved TRACLEER (bosentan) package insert."[54]

2. Apotex repeatedly attempted to buy samples but was refused by Actelion, and then attempted to buy Canadian Tracleer samples for its bioequivalence testing.

131. Generic drug maker Apotex Inc. ("Apotex") first attempted to purchase samples of Tracleer from its wholesale distributors and was refused.

132. On January 21, 2011, Apotex wrote to Actelion Pharmaceuticals, Inc., requesting to buy sample Tracleer directly from Actelion.

133. Apotex explained that:

- The samples sought "would be used to develop a generic equivalent of Tracleer Tablets to be submitted as an ANDA to US FDA."
- "The samples received would be used to analyzing [sic] the reference listed drug Tracleer and also conducting [sic] bioequivalence studies to compare the Apotex Bosentan generic product and Tracleer Tablets."
- "Apotex intends to develop this product for submission to the US FDA."
- The samples would not be used "for commercial sale and will not be sold in the U.S. to any patients."
- "All reasonably necessary controls will be put into place to control the access and handling of these bottles."
- Apotex promised that it would take all reasonable steps to control access to and proper handling of the samples under Actelion's REMS.[55]

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[54] Defendants Zydus Pharm. (USA) Inc.'s and Cadila Healthcare Ltd.'s Answer, Affirmative Defenses, Counterclaim and Jury Demand, at Answer ¶ 39, *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 11, 2013), ECF No. 80.

[55] Answer, Affirmative Defenses, and Counterclaim of Defendants Apotex Inc. and Apotex Corp., at Answer ¶ 41, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 24.

134. For the samples, Apotex was "willing to pay the price per bottle at market value."[56]

135. Apotex asked for a response within the next few weeks but received none.

136. On April 12, 2011, having received no response from Actelion, Apotex sent a follow-up letter, reiterating its request for samples to be used for bioequivalence testing. It again indicated that it was willing to pay full price. Apotex said the samples would be used "to investigate/experiment with and/or to develop a generic equivalent of Tracleer tablets to be submitted as an ANDA to the US FDA."[57] Apotex repeated that it would institute all appropriate safeguards to comply with Actelion's REMS, and that the Tracleer samples would not be re-sold: "The samples are not for commercial sale and will not be sold in the U.S. to any patient."[58]

137. Apotex again asked for a response within the next few weeks. Actelion never responded.

138. On April 21, 2011, Apotex sent a letter to the FDA describing its efforts to purchase Tracleer from Actelion. Actelion also informed the FDA that, as a fallback, it had obtained samples of the Canadian version of Tracleer (also manufactured by Actelion) and that it intended to conduct its bioequivalence testing by comparing its bosentan product to the Canadian samples. Apotex asked for the FDA's "feedback on the issue at the earliest to ensure that we can plan appropriately to submit the ANDAs on time."[59]

3. Actavis writes Actelion, requesting samples; Actelion refuses.

139. On September 6, 2011, another generic company, Actavis, Inc., sent a letter to Actelion, also requesting samples of Tracleer for analytical and bioequivalence studies. Like

[56] Actelion Brief in Support of Motion for Judgment on the Pleadings at 112, *Actelion Pharm. Ltd. v. Apotex Corp.*, No. 12-05743 (D.N.J. Jan. 16, 2013), ECF No. 44-1.
[57] *Id.* at 115.
[58] Apotex Answer, ECF No. 24, at ¶ 41.
[59] *Id. at* ¶ 48.

Apotex, Actavis offered to pay fair market value for the drug products and to reimburse Actelion for all reasonable costs associated with the request.

140. Actavis explained that it had been unable to buy the drug product through other market channels and promised to comply with Actelion's REMS.

141. On September 20, 2011, Actelion responded to Actavis, stating that the FDCA does not require Actelion to "relinquish its right to choose with whom it does business," and that Actelion was reserving that right "which exists independently of the restricted distribution program for Tracleer." Actelion advised that it had decided to deny Actavis's request.[60]

4. Roxane writes Actelion, requesting samples.

142. On January 12, 2012, a fourth would-be generic competitor, Roxane Laboratories, Inc., requested sample Tracleer from Actelion. Roxane's letter explained that it planned to use the samples "solely for developmental purposes to meet FDA requirements in support of an ANDA filing."[61] Roxane offered to buy the samples at market price.

143. Roxane approached Actelion directly because, after trying to buy samples from traditional wholesale distribution outlets, Roxane had been told that Tracleer was unavailable through normal distribution channels.

144. Actelion refused to allow Roxane (or other generics) to purchase samples from the wholesalers to whom Actelion distributes Tracleer, citing its REMS ETASU obligations.

145. Roxane explained that the FDA had specified that, for the purposes of developing a generic product, an ANDA filer must obtain the brand product from the RLD manufacturer.

[60] Actelion Brief, ECF No. 44-1, at 165.
[61] *Id*. at 151.

146. On February 10, 2012, Actelion responded to Roxane that Actelion "has the right to choose with whom it does business" and "has concluded that it will not be fulfilling Roxane's request."[62]

147. Shortly thereafter, Roxane obtained samples of Canadian Tracleer and conducted a pilot bioequivalence study of its prospective generic product using the Canadian samples.

5. The FDA approves Apotex's BE study protocols but requires it to use U.S. samples.

148. On February 21, 2012, the FDA sent Apotex comments on Apotex's proposed bioequivalence study protocol. It recommended certain changes to the protocol to ensure that the controls constituted an adequate substitute to those in Actelion's REMS. It did not comment on Apotex's intent to use Canadian Tracleer.

149. On May 21, 2012, the FDA stated that Apotex's proposed protocol was acceptable, provided that Apotex adopted a number of recommendations. One of its recommendations was that the studies "should be performed using the approved U.S. product as the reference product. It is not acceptable to use an approved Canadian drug product as described in your protocols."[63]

G. Summer 2012: Generics continue to request samples and announce intention to sue.

1. Apotex again requests samples, Actelion refuses.

150. On June 26, 2012, given the FDA's insistence that Apotex use U.S. samples, Apotex tried to obtain such samples from Actelion yet again. Apotex sent a third letter to Actelion requesting Tracleer samples.

[62] Roxane Labs., Inc.'s Answer, Affirmative Defenses, and Counterclaim, at Answer, ¶ 68, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 25.

[63] Roxane Answer, ECF No. 24, at ¶ 53.

151. Apotex noted that Actelion had not responded to its earlier requests to purchase Tracleer, and repeated that it was willing to pay market price for the samples and to implement all reasonably necessary controls for the access and handling of Tracleer under Actelion's REMS.

152. The letter noted that it had been seventeen months since Apotex first requested samples for bioequivalence purposes, and that "Actelion may not deny access to its RLD to thwart efforts by generic manufacturers from bringing competing products to market."[64]

153. Apotex explained that, while it preferred to avoid litigation, it was "unwilling to further delay its efforts to bring an important generic drug to market because of stonewalling on the part of Actelion."[65]

154. On July 2, 2012, Actelion responded to Apotex, announcing that it had decided not to fulfill Apotex's request for Tracleer tablets.

155. Actelion replied that its REMS requirements "do not provide for the sale of Tracleer tablets to Apotex," that "Actelion has the right to choose with whom it does business and to whom it will sell its products," and that Actelion was reserving that right "which exists independently of the REMS program for Tracleer."[66]

2. Apotex again informs the FDA it cannot obtain U.S. Tracleer samples.

156. In August 2012, Apotex submitted a revised bioequivalence protocol that incorporated all of the FDA's earlier recommendations, save one. Apotex explained that, because of Actelion's refusal to sell Apotex the requested samples of Tracleer, Apotex had been unable to procure the approved U.S. product to use in its bioequivalence study.

[64] Actelion Brief, ECF No. 44-1, at 118.
[65] Apotex Answer, ECF No. 24, at ¶ 56.
[66] Actelion Brief, ECF No. 44-1, at 143.

3. Apotex sends Actelion a draft complaint.

157. On August 1, 2012, Apotex wrote back to Actelion, noting that "Actelion's 'right to choose with whom it does business and to whom it will sell products' is not unlimited." Apotex continued, "[a]s a monopolist, Actelion may not thwart competition by withholding drug samples that are necessary for generic pharmaceuticals to bring competing products to market."[67] Apotex informed Actelion that it intended to file a civil action seeking injunctive relief, declaratory relief, and money damages. Apotex enclosed a draft complaint and threatened to sue under Section 2 of the Sherman Act if Actelion continued its refusal to sell Tracleer samples.

4. Roxane again requests samples, Actelion refuses and announces it intends to file suit.

158. Also on August 1, 2012, Roxane wrote Actelion again, urging Actelion to reconsider its refusal to sell Tracleer samples to Roxane for development purposes. Roxane stated that "Roxane has been unable to purchase this product, as it normally does in the ordinary course of business, from pharmaceutical wholesalers due to Actelion's restrictions." Accordingly, Roxane requested "to purchase supply from Actelion directly."[68] As counsel later explained in a court hearing, Roxane was willing to pay the retail published price that Actelion was charging "or, frankly . . . any price that was within the realm of reasonableness."[69] In its letter, Roxane noted that Actelion's refusal to sell Roxane samples violated antitrust laws, and that Roxane was prepared to "pursue all available options, including notifying the Federal Trade Commission and/or asserting antitrust and related claims against Actelion."[70]

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[67] *See* Apotex Answer, ECF No. 24, at ¶ 48.

[68] Roxane Answer, *Actelion v. Apotex*, 12-cv-5743 (D.N.J. Oct. 17, 2013), ECF No. 25, at ¶ 34.

[69] Transcript of Hearing on Motions at 49, *Actelion v. Apotex*, 12-cv-5743 (D.N.J. Oct. 17, 2013), ECF No. 93.

[70] Complaint for Declaratory Judgment ¶ 31, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Sept. 14, 2012), ECF No. 1.

5. Actelion strings along the generics and requests unnecessary information about their ANDAs to further its anticompetitive ends.

159. On August 9, 2012, Actelion replied to both Roxane and Apotex. It reiterated its refusals to sell (or permit others to sell) samples of Tracleer to Roxane on the alleged grounds that (1) it sought to protect its intellectual property rights, and (2) that doing so would violate its REMS distribution restrictions. It sought "clarification" regarding both companies' ANDA products and their communications with the FDA, while again claiming an unfettered right to choose with whom it does business and, on that basis, refusing to sell to Roxane or to Apotex.

160. On August 17, 2012, Apotex responded to Actelion's letter. Apotex noted that "several of Actelion's requests for 'clarification' appear unrelated to a good faith evaluation of Apotex's request and instead seem calculated to allow Actelion to obtain proprietary or strategic information belonging to Apotex, to which Actelion is not entitled."[71] Apotex nevertheless answered several of Actelion's questions, and then requested a final decision from Actelion regarding provision of the samples by August 25, 2012. Apotex indicated that it planned to file suit against Actelion if the answer was negative.

161. On August 21, 2012, Actelion wrote back to Apotex, claiming that Actelion remained open to considering Apotex's request but that to do so Actelion needed copies of Apotex's final testing protocols "to ensure that it indeed incorporates the necessary safeguards consistent with the Tracleer REMS." Actelion also demanded "[w]ritten confirmation from the FDA that it would be acceptable under the REMS for Actelion to supply Apotex with Tracleer samples for use in BE [bioequivalence] testing consistent with the final protocols." Actelion

[71] Actelion Brief, ECF No. 44-1, at 140.

challenged Apotex's "suggesti[on] that Actelion is required, as a matter of law, to sell it a patented product," and proposed a face-to-face meeting for further discussion.[72]

H. 2012–2013: Actelion and the generic companies litigate, seeking competing declaratory relief.

1. Actelion sues Apotex and Roxane.

162. In September of 2012, Actelion sued Apotex and Roxane in the United States District Court for the District of New Jersey.

163. At the time Actelion sued, Tracleer's average monthly wholesale price was about $3,000.

164. Actelion represented that Apotex and Roxane had demanded samples from Actelion so that they could develop competing products; that Actelion had not supplied the samples requested; and that Apotex and Roxane had threatened to file lawsuits (potentially seeking an injunction forcing Actelion to sell the generics samples and/or asserting antitrust claims) in order to obtain Tracleer samples.

165. Actelion argued that the relief it expected Apotex and Roxane to seek would be "in direct contravention of . . . the REMS for Tracleer" and "the well settled legal and commercial principle that companies have the right to choose with whom they will do business and to whom they will sell their products."[73] Actelion sought a judgment that Actelion had no duty to deal with Apotex or Roxane and that it was under no obligation to supply Tracleer samples to prospective generic competitors.

[72] *Id.* at 149.

[73] Actelion Complaint for Declaratory Judgment, at ¶ 4, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Sept. 14, 2012), ECF No. 1.

2. Apotex and Roxane counterclaim, alleging antitrust violations.

166. On November 27, 2012, Apotex and Roxane each answered and asserted counterclaims.

167. Apotex represented that it had identified the opportunity and need for a generic equivalent of Tracleer, that it had already developed a generic drug that it believed to be bioequivalent to Tracleer, and that it needed samples of Tracleer in order to perform the required bioequivalence testing so it could thereafter file an ANDA.

168. Apotex confirmed that it had repeatedly sought to purchase samples and Actelion had repeatedly denied those requests. Apotex stated that it had entered into good faith negotiations with Actelion in an attempt to resolve the dispute without resorting to litigation.

169. Apotex explained that, but for Actelion's refusal to sell it samples, Apotex would have filed an ANDA for a generic bosentan product by late 2011, and that it would have been in a position to obtain approval of that ANDA, at a minimum, before the '740 patent expired in November 2015.

170. Apotex asserted six affirmative defenses, including failure to state a claim, estoppel based on Actelion's own acts and omissions, the fact that Actelion's claims were barred by the FDCA and antitrust laws, as well as a failure to plead a claim under the Declaratory Judgment Act.

171. In its counterclaim, Apotex alleged that "Actelion has abused its monopoly power by denying Apotex the ability to purchase Tracleer samples for bioequivalence testing and [therefore] to submit an ANDA to FDA for a generic bosentan product."[74] Apotex asserted six causes of action (including three premised on violations of antitrust law) and sought "preliminary

[74] Apotex Counterclaim, ECF No. 24, at ¶ 56.

and permanent mandatory injunctive relief . . . compelling Actelion to sell Apotex sufficient quantities of Tracleer at market prices so that Apotex can perform bioequivalence testing."[75]

172. Roxane's answer and motion for declaratory judgment alleged that Actelion was using its REMS and the ETASU distribution restrictions as a pretext to block or delay generic competition in violation of FDA regulations, the antitrust laws, and state law. Roxane asserted twelve affirmative defenses, including failure to state a claim, lack of injury suffered by Actelion, and that Roxane's acts and omissions are protected under FDA regulations and other law.

173. Roxane alleged that Actelion had not only refused to sell it samples, but that Actelion had also prohibited its distributors from selling samples to Roxane. Roxane represented that "Actelion . . . refuses to allow Roxane to purchase samples either from Actelion or the wholesalers to whom Actelion distributes these drugs, citing their REMS. . . ."[76]

174. Roxane explained that it had FDA-approved safety protocols in place, and that it had already conducted a pilot bioequivalence study using Canadian Tracleer.

175. Roxane also pointed out that Actelion's Tracleer sales accounted for 90% of Actelion's total sales in 2012, and that the development and launch of a generic that would erode those sales was a major threat to Actelion. Roxane stated that Actelion's conduct had cost Roxane and those who pay for Tracleer by "forcing customers to pay hundreds of millions of dollars more for these drugs than if Roxane were not unlawfully prevented from developing lower cost generic alternatives."[77] Roxane further alleged that "[s]pecifically, because Actelion prohibits access to bioequivalence samples using its REMS program as a pretext, even in the presence of FDA-

[75] *Id.* at ¶ 30.
[76] Roxane Counterclaim, ECF No. 25, at ¶ 10.
[77] *Id.* at ¶ 3.

approved safety protocols and offers of compensation at retail prices, Actelion's conduct demonstrates predatory intent and has the effect of excluding potential competitors while preserving Actelion's dominant position."[78]

3. Actavis intervenes and counterclaims, also alleging antitrust violations.

176. On November 27, 2012, Actavis moved to intervene as a defendant and counter-plaintiff in the pending litigation. That motion was granted on December 19, 2012, and Actavis filed an answer and counterclaims on December 26, 2012.

177. In its counterclaim, Actavis represented that Actelion had refused to permit it to acquire necessary samples; that it was unable to obtain samples from other sources; that at no time had Actelion specified or offered to even discuss what specific safeguards would address its safety concerns, or what safeguards Actavis would have to meet in order to obtain testing samples from Actelion. Actavis, like Apotex and Roxane, asserted that Actelion's purported safety concerns were a pretextual fig leaf behind which Actelion tried to hide its true goal: blocking or delaying generic competition.

4. Actelion moves for judgment on the pleadings; Apotex, Roxane, and Actavis oppose.

178. On January 16, 2013, Actelion moved to dismiss the counterclaims and simultaneously moved to stay discovery.[79]

179. In moving to dismiss the generics' counterclaims, Actelion argued that:

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[78] *Id.* at ¶ 105.

[79] In opposing Actelion's motion to stay, the generics also reminded the Court that Actelion had an interest in prolonging the litigation for as long as possible: "As a monopolist with the exclusive right to manufacture and sell the . . . drug product[] at issue, Actelion has an overwhelming economic interest in perpetuating the status quo for as long as possible. Its request for a discovery stay is just another tactic to further delay the development of competing generic products." Defendants and Counterplaintiffs' Joint Sur-reply in Oppositions to Plaintiffs and Counterdefendants' Motion to Stay Discovery, at Motion to Stay 7-8, *Actelion Pharmaceuticals. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Feb. 19, 2013), ECF No. 53.

(a) the antitrust laws do not obligate Actelion to sell samples to firms with which it chooses not to do business, or to help potential rivals enter the marketplace;

(b) there was no history of dealing between the parties;

(c) there are other paths to the marketplace available to the potential generic competitors, including filing an NDA of application under 505(b)(2) (and so Tracleer samples are not an "essential facility");

(d) Actelion has a patent for Tracleer;

(e) Congress twice refused to impose an explicit duty to sell samples; and

(f) the drugs pose significant health and safety risks, which required distribution restrictions as a condition of FDA approval.

In short, Actelion argued that it was under no legal obligation to sell samples to its potential generic rivals when doing so would help those rivals get to market and would create generic competition.

180. Actelion argued, in part, that the FDA, via the REMS, "required" Actelion to make the distribution arrangements that it in fact made with Tracleer distributors. But, in truth, the REMS only restricts the *kinds* of patients to whom Actelion may be dispensed. Neither REMS, nor any other restriction imposed by the FDA, requires that Tracleer distributors only be allowed to sell to patients.

181. As to Actelion's arguments that generics could seek approval by filing a 505(b)(2) application, they could not have done so without obtaining samples. For products approved under 505(b)(2) to be deemed AB-rated (and therefore substitutable for the RLD at pharmacy counters), they must still be shown to be bioequivalent to the RLD—so samples would still be required. While products can be approved under 505(b)(2) without showing bioequivalence, they would not be substitutable (thus undermining the intent of the Hatch-Waxman framework). A bioavailability

"bridge" to the brand product would still be needed in order to take advantage of the RLD's safety and efficacy showings—which, again, would require samples.

182. On March 4, 2013, the generic companies jointly opposed Actelion's motion to dismiss the counterclaims. The generics argued that they sufficiently alleged violations of Section 2 of the Sherman Act because:

(a) they had adequately alleged that Actelion's refusal to provide samples was exclusionary;

(b) they had adequately alleged that Actelion's refusal to provide samples was an unjustified refusal to deal (under *Trinko* and *Aspen Skiing*, neither of which required prior dealing between the parties);

(c) they had adequately alleged that access to Tracleer samples was an essential facility (and that the "essential facilities" doctrine is still good law post-*Trinko*);

(d) patent law does not *per se* trump antitrust law and, by statute, is more appropriately considered *after* the filing of an ANDA;

(e) any professed safety concern was pretextual given Actelion's long history of providing samples to brand-name drug manufacturers and research hospitals; and

(f) Actelion's argument that generics could have obtained approval through another regulatory path, or that the samples were not strictly necessary, only raised disputes of fact that could not properly be resolved at the motion to dismiss stage.

5. Both the FTC and the Generic Pharmaceutical Association file *amicus* briefs supporting the generics' arguments.

183. On March 11, 2013, the Federal Trade Commission, the entity in charge of federal antitrust enforcement, filed an *amicus curiae* brief that largely tracked the arguments made by the generics.[80]

184. In its brief, the FTC called Actelion's alleged conduct "a troubling phenomenon," noting "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition."[81]

185. The FTC observed, correctly, that the unique regulatory framework that facilitates development and adoption of generic drugs "depends on generics firms' ability to access samples of brand products."[82]

186. The FTC concluded that "Actelion's position that it has a virtually absolute right to block generic access to its products . . . poses a significant threat to competition in the pharmaceutical industry" and that "Actelion's legal position, if adopted, could prove costly for consumers of prescription drugs."[83] It then described the regulatory framework, explained why actions that block generic access can violate antitrust laws, articulated why refusing to sell samples to generic rivals may constitute exclusionary conduct, and explained that conducting bioequivalence testing would not infringe Actelion's patent for Tracleer.

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[80] *FTC's Brief as Amicus Curiae, Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Mar. 11, 2013), ECF No. 61-2. The FTC noted that while it had not yet filed an enforcement action to address REMS-based withholding of samples, it continues to investigate and that this case in particular "may have much broader implications for the Commission's competition mission and the interests of consumers." *Id.* at 2-3.

[81] *Id.* at 1.

[82] *Id.*

[83] *Id.* at 1, 2.

187. In its *amicus* brief, also filed March 11, 2013, the Generic Pharmaceutical Association[84] explored the history and policy behind the Hatch-Waxman amendments, and noted that Actelion's actions in refusing to sell samples of Tracleer to generic companies undermined the statute's purpose: "In this action, Actelion seeks to give branded drug makers unreviewable power to decide whether to allow generic competition or maintain their monopoly. . . . It is no exaggeration to say that accepting Actelion's position would subject the current robust and competitive generic drug market to the whims of branded drug makers, rendering the ANDA process all but a dead letter . . . ."[85]

6. The FDA re-approves Apotex's safety protocols; Actelion still will not provide samples.

188. In May of 2013, while the motion to dismiss was pending, Apotex asked the FDA to re-approve the safety protocols it used in its bioequivalence testing. Later that month, Apotex received a letter from the FDA re-approving its safety measures. Apotex again contacted Actelion, reiterating its request for samples and attaching the FDA's letter. Actelion replied: "This changes nothing. You don't get it."[86]

[84] The Generic Pharmaceutical Association, which changed its official name to the Association for Accessible Medicines in 2017, is a trade association representing generic pharmaceutical and biosimilar companies. *See* ACCESSIBLE MEDICINES, https://accessiblemeds.org/.

[85] *Brief of Amicus Curiae Generic Pharmaceutical Association in Support of Defendants and Counterclaim Plaintiffs*, at 11, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr 1, 2013), ECF No. 59-3. The *amicus* brief further noted, "If Congress meant to give branded drug makers unreviewable discretion to deny potential generic entrants access to the reference samples necessary to complete the ANDAs that made the generic-drug revolution possible, it could hardly have chosen a more obscure and indirect method than the REMS safety protocols." *Id.* at 14.

[86] Transcript of Motions Hearing, ECF No. 93. at 45.

7. Zydus moves to intervene in the lawsuit.

189. On July 2, 2013, Zydus/Cadila filed a consent motion seeking to intervene in the litigation as Actelion had also denied them access to Tracleer samples.[87]

190. Zydus/Cadila represented that it had been trying to obtain U.S. Tracleer samples since at least 2010; that it had repeatedly tried to purchaser Tracleer from wholesale distribution channels so that it could conduct the necessary bioequivalence testing; that Tracleer distributors had not and would not supply Tracleer without Actelion's approval; and that, as a result, Zydus/Cadila "had to abandon their efforts to formulate a generic bosentan drug product for the United States market when it became apparent that FDA would only accept bioequivalence studies that compared a generic bosentan drug product to the version of Tracleer marketed in the United States."[88]

191. Zydus/Cadila reported that, between November 2009 and December 2010, two different pharmaceutical wholesalers confirmed that they could not sell the U.S. Tracleer product to Zydus/Cadila.

192. An order approving Zydus's intervention was entered on July 9, 2013.

[87] Consent Order Granting the Intervention of Zydus Pharm. (USA) Inc., and Cadila Healthcare Ltd. as Defendant and Counterplaintiff, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 2, 2013), ECF No. 75-1. In the interim, an additional company, Johnson Matthey Inc., moved for leave to intervene as a defendant and counterclaimant, alleging that Actelion had denied its request for samples of a different drug, Zavesca (generic name miglustat). That motion was granted by a consent order dated April 2, 2013. Consent Order Granting Johnson Matthey Inc.'s Motion to Intervene, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr. 2, 2013), ECF No. 67. Johnson Matthey's claims with regard to Zavesca samples parallel the claims of Apotex, Roxane, Actavis, and Zydus, but are not related to bosentan and therefore are not detailed here.

[88] Defendants Zydus Pharm. (USA) Inc., and Cadila Healthcare Ltd.'s Answer, Affirmative Defenses, Counterclaim and Jury Demand at Counterclaim, at ¶ 41, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 2, 2013), ECF 75-3.

I. Summer 2013: Apotex obtains a letter from the FDA approving its BE protocols.

193. On July 31, 2013, the FDA issued a "sample determination letter" to Actelion about Tracleer. This letter stated that the FDA had received a request from Apotex for help in obtaining supplies of branded Tracleer for the purposes of testing a proposed generic bosentan product against Tracleer; that the generic applicant had submitted study protocols that the FDA had determined included safety precautions for testing comparable to those set forth in Actelion's REMS program; and that the FDA would not consider it a violation of the REMS for Actelion to provide the Apotex with enough Tracleer that Apotex could perform the testing necessary to support an ANDA and otherwise meet the requirements for approval.

194. The FDA also reminded Actelion that the FDCA prohibits an NDA holder from using any ETASU to block or delay approval of a would-be generic competitor's product. The FDA stated that a "sufficient quantity" of Tracleer should be supplied to the generic applicant to conduct the necessary testing—and that the amount requested by the prospective generic applicant was the minimum quantity Actelion should provide.

J. Fall of 2013: The Court denies Actelion's motion to dismiss and the parties quickly settle.

195. On October 17, 2013, the District Court heard oral argument on Actelion's motion for judgment on the pleadings. During the hearing (and in post-hearing orders), the Court denied Actelion's motion to dismiss, ordered that the action shall proceed with discovery, and set a telephone conference with the Magistrate to discuss a proposed discovery schedule.

196. The Court refused to rule, as a matter of law, that Actelion's refusal to sell samples to its generic competitors was not illegal and could not, on the facts pleaded, constitute a violation of Section 2 or Section 1 of the Sherman Act, and therefore denied Actelion's motion. The Court observed:

> *Trinko* can't repeal Section 2. It survives. It's there and it's available, if the facts allow it, to prevent the improper maintenance and extension of a monopoly through improperly motivated conduct.
>
> ***
>
> If the [generics] can prove that [Actelion] is motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent, to use exclusive distribution agreements and to use a [sic] otherwise legitimate refusal to deal together to maintain and extend a monopoly, then they may very well make out a Section 2 claim.[89]

197. In so holding, the Court made the following statements:

- "I'm not entirely comfortable with the notion that, on the limited facts available to me, that you always have a right under all circumstances to refuse to sell samples to generic companies."[90]
- "[Y]our client did not say, 'I won't sell to you unless you go to the FDA, get their approval for me to sell it to you, and approval for your protocols, and, by the way, you're going to have to pay . . . for that. I'm not doing it.' You simply said 'We're just not going to sell,' right?"[91]
- "The problem here is—or the concern, I think, would be that the refusal to sell samples, coupled with the very restrictive—the exclusive distribution agreement, indeed, the banning of sales, unapproved sales, coupled together, mean that the patent-holder is extending its patent into the expiration period at patent level prices because it's effective[ly] excluded any generic competition?"[92]
- "[D]oesn't the regulatory system kind of assume that samples will be obtained in the normal course?"[93]
- "[W]hat I'm having difficulty [with] is . . . the notion that [Actelion's interpretation] somehow would allow a brand name manufacturer who has, I will call it, Section 2 intent to . . . confer upon them some kind of Section

[89] Transcript of Motions Hearing, at 116-17, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Oct. 31, 2013), ECF No. 96.
[90] *Id.* at 11.
[91] *Id.* at 19.
[92] *Id.* at 31.
[93] *Id.* at 33.

> 2 immunity where . . . conduct beyond [] a mere refusal to sell suggests an intent to extend or maintain a monopoly."[94]

198. The Court asked Actelion, point blank, whether, if the FDA issues a letter acknowledging that a generic's study protocols were adequate, Actelion would still refuse to sell samples to generics looking to conduct bioequivalence testing. Actelion, after some hemming and hawing about how it still would not have an obligation to sell to generics, eventually answered "yes."[95]

199. The court indicated that it would be preparing a substantive written opinion to supplement its order.

200. During the hearing, the parties referred to the existence of settlement discussions, but represented that "[t]here has been no progress made. There was an offer, it has been rejected . . . ."[96]

201. On October 29, 2013, Actelion entered into a Supply Agreement with Apotex.

202. Three days later, on November 1, 2013—before the Court issued its promised substantive written opinion—Actelion and Apotex settled on undisclosed terms. They dismissed all claims and counterclaims with prejudice.

203. Following a December 2013 settlement conference convened by the U.S. Magistrate Judge for the District Court, Actelion settled with the remaining generics in February 2014, also on undisclosed terms.

204. The settlements themselves are consequences of Actelion's anticompetitive actions and cannot serve to shield the unlawful conduct. The specific terms of these settlements are

[94] *Id.* at 38.
[95] *Id.* at 19.
[96] *Id.* at 19.

unknown to the plaintiffs, as is any effect those settlements may have had on events after their execution, including how those agreements may have impacted the dates of generic entry.

205. Actelion's anticompetitive conduct both before and after entering into the supply and settlement agreements with each of these generics, however, had already accomplished its objective – delaying generic entry. As a result, Plaintiffs and members of the proposed class were forced to pay higher prices than they otherwise would have had generic entry occurred earlier.

K. 2013–2016: The FDA repeatedly confirmed that providing samples would not violate the REMS.

206. Even after Actelion settled with Apotex, Zydus/Cadila, Actavis and Roxane, it continued to block and delay access to samples of Tracleer as to other generic manufacturers. Actelion's anticompetitive conduct clearly presents the risk of reoccurrence.

207. On September 1, 2015, the FDA issued two more sample determination letters, each relating to a different generic company's request for Tracleer U.S. samples. The letters contained the same information as its initial letter.

208. On October 16, 2015, the FDA issued a fourth sample determination letter, referring to yet another generic company's request for Tracleer U.S. samples. Again, the letter was identical in substance to the earlier letters.

209. On January 29, 2016, the FDA issued a fifth sample determination letter, addressing a fifth generic company's request for Tracleer U.S. samples, and conveying the same information. Thus, even after its 2013 and 2014 settlements, Actelion continued to withhold samples of Tracleer from would-be generic competitors. In total, the FDA issued five Safety Determination Letters to Actelion concerning requests for sample quantities of U.S. Tracleer. Upon information and belief, each letter refers to a different would-be generic applicant's request for samples.

210. Each letter informs Actelion that it would not violate the Tracleer REMS by providing samples and advises Actelion to provide a sufficient quantity of Tracleer to allow generics to conduct the necessary testing.

211. In each of the five letters, the FDA told Actelion that the specific protocols each generic company proposed to use in its clinical trials of Tracleer and its generic product were adequate to protect the safety of test subjects.

L. Had Actelion not prevented the generics from obtaining Tracleer U.S. samples, one or more Tracleer generics would have been available in November 2015, or earlier than April 2019.

212. The '740 patent was set to expire November 20, 2015. But for Actelion's refusal to allow the generics to purchase samples, one or more generics would have been available in November 2015 or, in any event, earlier than April 2019.

213. In 2011, the median review time to approval for an ANDA was 30 months. In 2012, it was 31 months. In 2013, it was 36 months.[97]

214. In February 2013, Apotex, Roxane, and Actavis represented that their "efforts to develop and market generic alternatives to Actelion's products have already been delayed for months, or, in some cases, years"[98] and that—in the absence of Actelion's anticompetitive actions—generic entry should occur, at the very latest, when the '740 patent expired on November 20, 2015.

[97] Press Release, Generic Pharm. Ass'n. (GPhA), *Statement by David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, GPhA, Regarding the Senate HELP Hearing on GDUFA* (Jan. 28, 2016), https://www.pharmacytimes.com/association-news/statement-by-david-gaugh-senior-vice-president-sciences-and-regulatory-affairs-gpha-regarding-the-senate-help-hearing-on-gdufa.

[98] Defendants' and Counterplaintiffs' Joint Memorandum in Opposition to Plaintiffs' and Counterdefendants' Motion to Stay Discovery, at 2, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Feb. 5, 2013), ECF No. 49.

1. Apotex would have launched in November 2015.

215. In and around 2012, and while the parties were litigating, Apotex was one of the top ten generic companies, by sales, in the U.S. Apotex employed over 7,500 employees worldwide and sold products in 115 countries and territories. It produced more than 300 generic pharmaceuticals in thousands of dosages and formulations. Apotex had 235 approved ANDAs in the U.S. and filed 40-50 new ANDAs annually. Apotex also spent over $800 million in litigation costs in 1,000 lawsuits over the past ten years to bring generics to market sooner.

216. During litigation, Apotex represented that—if it had access to the necessary samples—it would have filed an ANDA by late 2011 and would have obtained approval and launched no later than November 2015:

> But for Actelion's refusal to sell such samples, Apotex would have filed an ANDA for a generic bosentan product by late 2011 and would have been in a position to obtain approval of that ANDA, at a minimum, before the protection for the '740 Patent expires in November 2015.[99]

217. During oral argument, Apotex's counsel represented that the time from ANDA filing to approval "can be, you know, at least two years, maybe 30 months."[100] "So every month of delay that they buy now by preventing potential generic competitors from getting access to drugs that they need for bioequivalence is another month later that the process is pushed down the road. Because the FDA is going to take the time that the FDA needs to evaluate the ANDA, and it doesn't happen overnight."[101]

2. Actavis would have launched in November 2015, or earlier than June 2019.

218. As of 2012, when the parties began litigating:

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[99] Apotex Counterclaim, ECF No. 24, at ¶ 59.

[100] Transcript of Hearing on Motion to Stay, at 18, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr. 29, 2013), ECF No. 71.

[101] *Id.*

- Actavis marketed more than 750 products globally, operating in more than 60 countries;
- Actavis's generics business reported net revenues of $4.45 billion, accounting for over 75% of the company's total revenues and making it one of the top give generic companies in the world;
- Actavis launched more than 1,000 generics produced globally, including 13 exclusive launches in the U.S.;
- Actavis filed 45 new ANDAs with the FDA; and
- Actavis had more than 185 ANDAs on file, including 49 first-filer opportunities (33 of which were potentially exclusive).

219. By November 2012, Actavis had actively developed a proposed generic bosentan product. It had made a considerable investment in doing so, including conducting various required studies, developing a prototype, and manufacturing "pilot bio-batches." Actavis represented that "once bioequivalence studies are complete, [Actavis] will seek FDA approval."[102]

220. Actavis publicly represented in its 2012 Annual Report that, but for Actelion's wrongful conduct, Actavis would have promptly completed studies showing the bioequivalence of its formulation with Tracleer and filed an acceptable ANDA with the FDA in late 2011 or early 2012.

221. On April 26, 2019, the FDA approved Watson/Actavis's ANDA for Tracleer. Watson/Actavis[103] launched its generic version of Tracleer in June 2019.

222. Given mean approval times, Actavis's ANDA would have very likely been approved inside of 36 months, or in any event well before the Tracleer patent expired. In the

[102] Memorandum in Support of Motion of Actavis Elizabeth LLC to Intervene as Defendant and Counterplaintiff at 12, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 27-1.

[103] Watson was acquired by Actavis in 2012, and Actavis was subsequently acquired by Teva Pharmaceuticals in 2016.

absence of Actelion's conduct, Watson or its purchaser Actavis would have launched on or around November 20, 2015, or in any event, earlier than June 2019.

3. Roxane would have launched in November 2015, or earlier than June 2019.

223. Roxane intended to file an ANDA for bosentan.

224. Roxane stated in its litigation with Actelion, "In order to prepare its bosentan product . . . and file its ANDA[], Roxane needed to secure samples of bosentan . . . for use in bioequivalence studies."[104]

225. In 2011, Roxane tried to obtain Tracleer samples through normal distribution channels but was unable to do so. From then on, it repeatedly sought to purchase samples from Actelion at market rates. Actelion refused to sell Roxane the requested samples.

226. In November 2012, Roxane estimated that, absent Actelion's obstructionist conduct, "Roxane would have been able to introduce a lower-priced competing bosentan product at least one year earlier than it will now be able."[105]

227. On April 26, 2019, the FDA approved an ANDA for Tracleer submitted by West-Ward, a company owned by Hikma, which also owns Roxane[106] West-Ward/Hikma launched its generic version of Tracleer in June 2019.

228. In the absence of Actelion's conduct, Roxane and/or its purchaser West-ward/Hikma would have filed an ANDA and would very likely have obtained approval and launched on or around November 20, 2015, or in any event earlier than 2019.

[104] Roxane Counterclaim, ECF No. 25, at ¶ 66.
[105] *Id.* at ¶ 79.
[106] West-Ward has been a wholly owned U.S. affiliate of Hikma Pharmaceuticals PLC since at least 2001. Hikma/West-Ward purchased Roxane Laboratories, Inc. in 2016.

4. Zydus would have launched by November 2015, or earlier than May 2019.

229. Zydus intended to file an ANDA earlier than it did for Tracleer and sought samples from wholesalers and Actelion from 2009 on.[107] After repeatedly being denied access to samples, it stopped pursuing its ANDA.

230. On April 26, 2019, the FDA approved Zydus/Cadila's ANDA for Tracleer. Zydus launched its generic version of Tracleer on or about May 1, 2019.

231. In the absence of Actelion's conduct, Zydus would have filed an ANDA earlier and would have obtained approval and launched on or around November 20, 2015, or in any event, earlier than May 2019.

5. Other generics would have launched by November 2015, or earlier than April 26, 2019.

232. On April 26, 2019, the FDA approved ANDAs and a REMS for bosentan by Alvogen Pine Brook, Amneal, Natco, Par, and Sun.

233. Alvogen Pine Brook, Amneal, Par, and Sun all launched their generic versions of Tracleer on or about April 26, 2019.

6. In the absence of Actelion's conduct, these generic companies would have filed an ANDA earlier and would have obtained approval and launched on or around November 20, 2015, or in any event, earlier than April 26, 2019.Actelion anticipated, and prepared for, generic competition as early as November 2015.

234. The '740 patent was set to expire November 20, 2015. Actelion expected multiple generic competitors to launch at that time if not before.

235. A brand company may compete with generics once a generic launches by selling its own generic product (an "authorized generic" or "AG") manufactured under its NDA. AGs are often the same brand pills packaged in a different bottle and sold at a lower price point. Sometimes

[107] Zydus and Cadila Counterclaim, ECF No. 80, at ¶ 37.

the brand may hire another company to manufacture the authorized generic (under the NDA). Selling a "generic" product permits the brand company to compete for some percentage of the generic sales.

236. Upon information and belief, at some point in 2015, Actelion and the FDA discussed the possibility of Actelion launching an authorized generic version of Tracleer.

237. On December 4, 2015, in approving a modification to Actelion's REMS, the FDA noted that "[a]n authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission."[108]

238. In the same letter, the FDA reminded Actelion that the FDAAA "prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval [of an ANDA] . . . . A violation of this provision . . . could result in enforcement action." Enforcement actions can include warning letters, injunctions, criminal prosecution under Section 301 of the FDCA, or criminal files under The Criminal Fine Enforcement Act of 1994.

239. On October 20, 2017, Actelion's REMS was modified to add an authorized generic for Tracleer tablets. On or about June 3, 2019, Actelion launched an authorized generic version of Tracleer through its subsidiary, Co-Therix. Absent Actelion's anticompetitive conduct, it would

[108] December 4, 2015 Letter from Mary Ross Southworth, Deputy Dir. for Safety, Office of Drug Evaluation I, Center for Drug Evaluation and Research to Frances Duffy-Warren, Assoc. Dir., Drug Regulatory Affairs, at 14. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021290Orig1s027,s029ltr.pdf.

have launched an authorized generic version of Tracleer earlier, at or around the same time other generic manufacturers launched a generic version of Tracleer.

240. As a result of Actelion's anticompetitive conduct, no generic versions of Tracleer received FDA approval until April 26, 2019, even though Tracleer is a billion-dollar drug and lost patent protection in November 2015.

M. Actelion's scheme destroyed competition and caused damages to Plaintiffs and the class.

241. In enacting the Hatch-Waxman scheme, Congress determined that purchasers and consumers were best served by accelerated generic entry into the market. Blocking or delaying a generic manufacturer's access to drug samples obstructs a clear market benefit.

242. Samples of the brand drug (*i.e.*, the FDA-approved, U.S. version, of the reference-listed drug) are essential to competition. Nothing else will do. Without these samples, a generic company cannot satisfy the FDA's bioequivalence requirements, cannot file an ANDA, cannot obtain FDA approval, cannot launch a generic drug, and cannot compete in the market.

243. Generic companies could not have obtained samples of Tracleer through a cooperative prescribing physician or pharmacist. A physician who wrote a prescription for Tracleer tablets, or a pharmacist who dispensed them, outside the usual course of their professional practice and/or other than to a bona fide patient could have faced felony charges under federal and state law, as well as de-licensure. A company that obtained samples by those routes could also have been held criminally liable.

244. Generic companies also could not have replicated samples of Tracleer or purchased samples from a different company. For purposes of filing an ANDA, the proposed generic product must be compared to the approved RLD – no substitutions or duplicates are accepted.

245. Generic companies could only have obtained the necessary samples from Actelion or a certified distributor. Actelion prevented generics from purchasing samples through either path: Actelion refused to sell samples to the generics directly for varying periods of time; it also prevented its distributors from selling samples to the generics by withholding its consent and/or outright prohibiting them from doing so. Obtaining controlled substances, including bosentan, without "a prescription issued . . . in the usual course of professional treatment or in legitimate and authorized research," is a violation of federal law with potential criminal liability for physicians and pharmacists who knowingly write or fill prescriptions outside those bounds.[109] Many states also prohibit physicians from writing prescriptions outside the usual course of professional treatment, and/or pharmacists from knowingly filling them.[110]

246. Actelion had no legitimate interest in excluding generic companies' access to samples of U.S. Tracleer. Its only interest was maintaining its monopoly by delaying generic entry.

247. Actelion's interest in protecting its intellectual property rights cannot justify its refusal to allow generic manufacturers to purchase samples. Federal law provides that pre-market testing performed by a generic manufacturer does not constitute an act of patent infringement.[111] In contrast, by statute, the filing of an ANDA constitutes a technical act of infringement (such that it permits a brand company with good cause to sue for infringement, and in turn a generic to challenge the patent or explain why it does not infringe). Here, withholding the samples prevented generics from filing an ANDA at all, so there could be no act of infringement. And Actelion has had no remaining intellectual property rights over bosentan since November 2015.

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[109] *See* 21 C.F.R. 1306.04 and 21 U.S.C. § 829.

[110] *See, e.g.*, Cal. Health and Safety Code §§ 11173, 11153; Mass. Gen. Laws Ch. 94C, § 19; N.Y. Public Health Law §§ 3331, 3335; Ohio Admin. Code 4729-5-30; Or. Admin. R. 855-019-0210.

[111] *See, e.g.*, 35 U.S.C. § 271(e)(1).

248. It made no economic sense for Actelion to refuse to allow generics to purchase its product. Actelion is in the business of selling drugs. The generics offered to pay market price and, in some instances, additional costs. Forgoing those sales is to forgo profits from those sales. Refusing to make a sale at the market price or higher makes no sense—unless one is trying to harm its competitors.

249. Actelion could easily have provided the samples, simply by doing what it does every day: sell Tracleer to purchasers at market price. It could have done so profitably.

250. The quantities required by ANDA filers for testing purposes are small, and Actelion has never claimed it had inadequate supply or insufficient capacity to file the generic companies' orders.

251. Actelion deployed its REMS for its anticompetitive ends. It had no legitimate safety concerns that could not have been alleviated through discussions between the parties or imposing reasonable conditions of the sale of the product (not that it ever tried to pursue this path with generics). In fact, Actelion did sell, or permit to be sold, samples to other research entities outside of its REMS. Meanwhile, the FDA repeatedly confirmed that allowing generic manufacturers to purchase Tracleer samples would not violate Actelion's REMS or ETASU. Actelion's safety concerns were pretextual; Actelion discriminated against the generics as would-be customers because the generics posed a competitive threat to Actelion's monopoly.

252. Actelion's right "to choose with whom it does business" is not unlimited: Actelion may not refuse to do business with a company for anticompetitive reasons. And there is no procompetitive reason that makes sense. The only explanation for Actelion refusing to sell Tracleer samples to the generic manufacturers is that it did so to block or delay competitors from entering

the market and thereby prolong its monopoly. This conduct was irrational but for its anticompetitive effects.

253. Actelion's conduct in preventing and delaying the generics from obtaining samples had detrimental effects on consumers and the market. As a result, less expensive generic versions of bosentan were excluded from the market for years after its only patent expired. Actelion's conduct gave purchasers no choice but to pay for branded Tracleer at supra-competitive prices.

254. There is no concern that allowing generic manufacturers access to samples of the brand would lessen the incentive for both entities to invest in developing their products. Actelion had already manufactured quantities of Tracleer and put them into public commerce. Actelion would not have had to, for example, embark on a separate process for creating a new product to sell to generic manufacturers. It simply had to refrain from preventing its distributors from selling the product to them. Allowing access to samples would only serve to bring the generics' less expensive competing product to market sooner.

255. There is no legitimate, non-pretextual, procompetitive business justification for Actelion's refusal to sell samples of Tracleer to generic manufacturers. Its refusal to sell was entirely predicated on its anticompetitive goals.

256. When it suited their needs, Actelion openly engaged with entities that sought to purchase samples of Tracleer, including researchers who wanted to study the drug. It provided Tracleer samples to non-competitors. Yet it refused to permit generic manufacturers (*i.e.*, would-be competitors) to obtain samples.

257. It is not surprising that Actelion had not, before the generics requested samples, engaged in a prior course of dealing with generic manufacturers as (1) Tracleer was the first drug product Actelion had ever sold in the U.S., (2) generic companies typically only seek to purchase

branded drugs in connection with pursuing their ANDAs, and (3) there would have been no reason for Actelion to deal with generic manufacturers before receiving their requests for samples. The requests for samples were likely the first opportunity for any business to be done between Actelion and generic manufacturers.

258. Actelion has acknowledged that its refusal to allow the generics to buy Tracleer samples (either from itself or from its distributors) was intended to impede its competitors and prolong its monopoly. Indeed, it has aggressively stood on its right to do so:

- ". . . companies such as Actelion are under no duty to deal with a competitor."[112]
- "There is no provision in the REMS statute that the owner of a drug subject to a REMS program is required to provide samples of its drug upon the request of a potential competitor."[113]
- "[T]here are . . . business justifications for declining access."[114]
- "The sole purpose of these proposed judicially-forced sales is to make it easier for the potential generic competitors to test and copy Actelion's products."[115]
- "Actelion is under no duty to sell its patented products to potential competitors . . . ."[116]
- "[T]he generics . . . want access to the very product that they want to test, copy, and then introduce into that market to compete with Tracleer."[117]
- ". . . it's perfectly appropriate for a monopolist to decide it does not want to set up – help a competitor set up and take away its business. *That is legitimate for a monopolist to do*. . .. and I think Ms. Reeves even quoted the portion of *Christy* that talks about the only motive pled there was a motive to make more money. There's nothing wrong with that."[118]

[112] Actelion Complaint, ECF No. 1, at ¶ 35.
[113] *Id.* ¶ 36.
[114] *Id.* ¶ 45.
[115] Actelion Brief, ECF No. 44-1, at 1.
[116] *Id.* at 3.
[117] Transcript of Motions Hearing, ECF No. 96, at 31.
[118] *Id.* at 108 (emphasis added).

259. Apotex, Roxane, and Actavis have all acknowledged the anticompetitive effects of Actelion's scheme, including the prejudice to the public that results from anticompetitive delays:

> [A] discovery stay would prejudice the public . . . by prolonging this litigation and further delaying the approval and sale of generic drugs that would compete with Actelion's Tracleer []. During an additional period of delay, Actelion would continue to reap monopolist's profits; patients would continue to pay artificially high prices for Tracleer []; and [] Counterplaintiffs would continue to forego profits on generic versions of those drugs.[119]

260. Actelion's scheme was intended to impede generic competition to Tracleer, and it succeeded in doing so.

261. Actelion's overarching scheme has suppressed competition by blocking and delaying generics from the most efficient means of competition under the applicable statutes and regulations.

262. As a result of Actelion's conduct, Plaintiffs and the class have been prevented from:

(a) purchasing less-expensive generic bosentan instead of more expensive branded Tracleer earlier,

(b) purchasing generic bosentan at a lower price earlier, and

(c) receiving discounts for purchases of branded bosentan, because earlier competition from generics at lower prices would likely have forced Actelion to reduce the price of branded bosentan to some degree, either directly or through discounts.

263. During the relevant period, Plaintiffs and the class purchased substantial amounts of bosentan. Because of Defendants' illegal conduct, Plaintiffs and the class were compelled to pay artificially inflated prices for their bosentan requirements due to the delay in generic entry.

[119] Counterplaintiffs' Joint Memorandum, ECF No. 49, at 1.

These prices were substantially higher than they would have been absent the illegal conduct alleged in this complaint.

264. Plaintiffs and the class have thus sustained substantial damages to their businesses in the form of overcharges, the exact amount of which will be the subject of proof at trial.

N. Effects on Interstate and Intrastate Commerce

265. At all material times, Tracleer, manufactured and sold by Actelion, was promoted, distributed, sold, and shipped in a continuous and uninterrupted flow of commerce across state lines and sold to customers located outside its state of manufacture.

266. During the relevant time period, in connection with the purchase and sale of Tracleer, monies as well as contracts, bills, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

267. During the relevant time period, various devices were used to effectuate the illegal acts described above, including United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Actelion's activities, as alleged in this complaint, were within the flow of, and have substantially affected, interstate commerce.

O. Actelion possesses monopoly power over the bosentan market.

268. At all relevant times, Actelion has maintained monopoly power over bosentan: it had the power to raise and/or maintain the price of bosentan at supra-competitive levels without losing substantial sales. Actelion also possessed complete control over the ability of competitors to obtain samples of the drug and thus enter the market in a way that is economically feasible, further adding to the strength of Actelion's monopoly power.

269. Would-be competitors cannot obtain the Tracleer samples they need, and they cannot create their own as the required bioequivalence testing of an ANDA product must be performed in comparison with the approved NDA Tracleer tablets that Actelion makes.

270. To the extent that Plaintiffs and the class are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Tracleer and any therapeutically equivalent ("AB-rated") bosentan generic manufactures (none are currently on the market). This allegation is entirely consistent with Actelion's own description of the relevant market, which it has conceded is "[the] market for bosentan."[120]

271. Through the sale of Tracleer, Actelion has had a 100% market share in the relevant market at all times. As Actelion has stated, Tracleer is the "first and only approved dual endothelin receptor antagonist."[121] Tracleer is the only branded bosentan drug approved to treat PAH. There are no generic competitors to Tracleer and there are no other reasonably interchangeable drug products available to prescribing physicians for the indications for which Tracleer is prescribed.

272. Given the nature of the relevant market, Actelion needed to control *only* Tracleer and any therapeutically equivalent generics of Tracleer—and no other products—to maintain the price of Tracleer profitably at supra-competitive levels.

273. Actelion has used its market power to maintain premium pricing for Tracleer since the drug's inception. At all relevant times, Actelion sold branded Tracleer well in excess of both marginal cost and of the competitive price and has enjoyed unusually high profit margins. Tracleer is extremely expensive, with an average monthly wholesale price of approximately $3,000 per patient.

274. Only the market entry of a competing, AB-rated generic equivalent version of Tracleer would make Actelion unable to profitably maintain its prices for Tracleer without losing

[120] *See* Transcript of Motions Hearing, ECF No. 96, at 32.
[121] Roxane Counterclaim, ECF No. 24, at ¶ 95.

substantial sales. But the only feasible way for a generic competitor to enter this market required obtaining a sample of Tracleer, and Actelion completely controls its distribution.

275. Actelion has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved bosentan drug products by—among other unlawful tactics—preventing potential competitors from obtaining samples and active pharmaceutical ingredient ("API") supplies, which are necessary for formulating a generic version of the drug. This conduct has kept the market price for FDA-approved bosentan artificially high.

276. Actelion's conduct forced consumers who needed bosentan to purchase Tracleer at artificially high and noncompetitive price levels and denied those consumers the availability of a lower-cost generic bosentan product. Consumers who needed bosentan were forced to purchase Tracleer at artificially high and noncompetitive prices and were denied the availability of a lower cost generic bosentan product. Purchaser class plaintiffs were harmed as a result of Actelion's conduct.

277. Actelion had a significant incentive to maintain its monopoly over bosentan and keep prices artificially high. Tracleer was a blockbuster drug for Actelion. Sales of Tracleer have accounted for a large percentage of the company's revenues. In 2013, Tracleer sales in the United States were $595 million. In 2014 they were $562 million.

278. The relevant geographic market is the United States and its territories.

279. At all relevant times, Actelion enjoyed high barriers to entry with respect to the above-defined relevant market.

280. A small but significant, non-transitory price increase to Tracleer by Actelion would not have caused a significant loss of sales to other drugs or products used for similar purposes,

with the exception of therapeutically equivalent generic versions of bosentan, had any been available.

281. Bosentan does not exhibit significant, positive cross-price elasticity of demand with any other endothelin receptor antagonist used for treatment of PAH, but it would likely exhibit significant, positive cross-price elasticity of demand with AB-rated generic versions of Tracleer.

VII. CLASS ACTION ALLEGATIONS

282. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the antitrust, unfair competition, and consumer protection laws of the states listed below (the "Indirect Purchaser States"), and as representative of a class defined as follows:

> All persons and entities in the Indirect Purchaser States and territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, at any time during the period from November 20, 2015 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

283. Excluded from the class are:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;

c. all persons or entities who purchased Tracleer for purposes of resale;

d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. any "flat co-pay" consumers whose purchases of Tracleer were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. pharmacy benefit managers; and

g. all judges assigned to this case and any members of their immediate families.

284. Members of the class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiffs believe that the class numbers in the thousands at least and is geographically spread across the nation. Further, the identities of members of the class will be readily identifiable from information and records in the possession of Actelion.

285. Plaintiffs' claims are typical of the claims of members of the class. Plaintiffs and all members of the class were damaged by the same wrongful conduct by Actelion, and all paid artificially inflated prices for Tracleer and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

286. Plaintiffs will fairly and adequately protect and represents the interests of the class. Plaintiffs' interests are coincident with, and not antagonistic to, the class.

287. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

288. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

289. Questions of law and fact common to the class include:

(a) whether Actelion unlawfully maintained monopoly power through all or part of its overarching scheme;

(b) whether Actelion's anticompetitive scheme suppressed generic competition to Tracleer;

(c) as to those parts of Actelion's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Actelion's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which bosentan is sold;

(d) whether direct proof of Actelion's monopoly power is available, and if available, whether it is sufficient to prove Actelion's monopoly power without the need to also define a relevant market;

(e) to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;

(f) determination of a reasonable estimate of the amount of delay Actelion's unlawful monopolistic, unfair, and unjust conduct caused;

(g) whether Actelion's scheme, in whole or in part, has substantially affected interstate commerce;

(h) whether Actelion's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and members of the class in the nature of overcharges; and

(i) the quantum of overcharges paid by the class in the aggregate.

290. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently,

and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

291. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 2 OF THE SHERMAN ACT

292. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.

293. At all relevant times, Actelion possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Actelion possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

294. Through its overarching anticompetitive scheme, as alleged above, Actelion willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiffs and the class. Actelion's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for bosentan in the United States.

295. Actelion accomplished its scheme by refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer. It did so in order to lengthen the period in which Actelion's brand Tracleer could monopolize the market and make supra-competitive profits.

296. Had Actelion competed on the merits instead of unlawfully maintaining its monopoly in the markets for bosentan, one or more ANDA generics and an authorized generic of Tracleer would have been available in November 2015, or in any event, earlier than April 2019. Plaintiffs and the class members would have substituted lower-priced generic Tracleer for the higher-priced brand-name Tracleer for some or all of their Tracleer requirements and would have paid substantially lower prices for brand-name Tracleer and generic bosentan.

297. The goal, purpose, and effect of Actelion's overarching anticompetitive scheme was to block and delay generic drugs from entering the market for bosentan, extend its dominance in that market, and maintain Tracleer's prices at supra-competitive levels. It has had the further effect of depriving the market of competition.

298. Actelion's scheme substantially harmed competition in the relevant market and was an unreasonable restraint of trade.

299. There is and was no non-pretextual, procompetitive justification for Actelion's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Actelion could assert, the scheme is and was broader than necessary to achieve such a purpose.

300. But for Actelion's illegal conduct, competitors would have begun marketing generic versions of Tracleer beginning in November 2015, or earlier than April 2019. Plaintiffs' allegations comprise a violation of Section 2 of the Sherman Act, in addition to state laws as alleged below.

301. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a), Plaintiffs and the class seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

302. Actelion has defended the anticompetitive conduct alleged herein, which makes it highly susceptible to reoccurrence. Actelion should be enjoined from denying samples of Tracleer, or other branded drugs, to competitors, in order to block or delay competition. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, Plaintiffs and the class further seek equitable and injunctive relief to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

VIOLATIONS OF STATE ANTITRUST LAWS

303. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

304. The following second through twenty-sixth claims for relief are pleaded under the antitrust laws of each State or jurisdiction identified below, on behalf of the class, and arise from Defendants' exclusionary, anticompetitive scheme designed to create and maintain a monopoly for Tracleer and its generic substitutes.

305. Although each individual count relies upon state law, the essential elements of each state antitrust claim are the same. The above-alleged conduct which violates the federal Sherman Antitrust Act will, if proven, establish a claim under each of the state laws cited below.

306. Through its anticompetitive overarching scheme and conduct described more fully above, Defendants willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiffs and the class. This anticompetitive conduct was undertaken with the specific intent to maintain a monopoly in the bosentan market in the United States.

307. Defendants accomplished their goals by, *inter alia*, refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic

entry of bosentan. It did so in order to lengthen the period in which Actelion's brand Tracleer could monopolize the market and make supra-competitive profits.

SECOND CLAIM FOR RELIEF
VIOLATION OF ARIZONA'S UNIFORM STATE ANTITRUST ACT,
ARIZ. REV. STAT. § 44-1401, *et seq*.

308. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

309. By reason of the conduct alleged herein, defendants have violated Title 44, Chapter 10 of the Arizona Revised Statutes. ARIZ. REV. STAT. § 44-1401, *et seq*.

310. Under Arizona law, "[t]he establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within this state, by any person for the purpose of excluding competition or controlling, fixing or maintaining prices is unlawful." ARIZ. REV. STAT. § 44-1403.

311. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Arizona, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

312. Defendants' violations of Arizona law were flagrant.

313. Defendants' unlawful conduct substantially affected Arizona's trade and commerce.

314. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

315. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available under Arizona Revised Statutes Section 44-1401, *et seq*.

THIRD CLAIM FOR RELIEF
VIOLATION OF THE DISTRICT OF COLUMBIA ANTITRUST ACT,
D.C. CODE § 28-4501, *et seq*.

316. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

317. The policy of the District of Columbia Code, Title 28, Chapter 45 (Restraints of Trade) is to "promote the unhampered freedom of commerce and industry throughout the District of Columbia by prohibiting restraints of trade and monopolistic practices." D.C. CODE § 28-4501.

318. Members of the class purchased Tracleer within the District of Columbia during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

319. Under District of Columbia law, indirect purchasers have standing to maintain an action under the antitrust provisions of the D.C. Code based on the facts alleged in this complaint, because "[a]ny indirect purchaser in the chain of manufacture, production or distribution of goods . . . shall be deemed to be injured within the meaning of this chapter." D.C. CODE § 28-4509(a).

320. Defendants monopolized or attempted to monopolize the market for bosentan within the District of Columbia, in violation of D.C. Code § 28-4501, *et seq*.

321. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in the District of Columbia and are entitled to all forms of relief, including actual damages, treble damages, as well as interest and reasonable attorneys' fees and costs.

FOURTH CLAIM FOR RELIEF
VIOLATION OF THE ILLINOIS ANTITRUST ACT,
740 ILL. COMP. STAT. ANN. 10/3(1), *et seq*.

322. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

323. The Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq.*, aims "to promote the unhampered growth of commerce and industry throughout the State by prohibiting restraints of trade which are secured through monopolistic or oligarchic practices and which act or tend to act to decrease competition between and among persons engaged in commerce and trade . . . ." 740 ILL. COMP. STAT. ANN. 10/2.

324. Members of the class purchased Tracleer within the State of Illinois during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

325. Under the Illinois Antitrust Act, indirect purchasers have standing to maintain an action for damages based on the facts alleged in this complaint. 740 ILL. COMP. STAT. ANN.10/7(2).

326. Defendants further unreasonably restrained trade or commerce and established, maintained or attempted to acquire monopoly power over the market for bosentan in Illinois for the purpose of excluding competition, in violation of 740 Illinois Compiled Statutes 10/1, *et seq*.

327. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Illinois and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' fees and costs.

FIFTH CLAIM FOR RELIEF
VIOLATION OF THE IOWA COMPETITION LAW
IOWA CODE § 553.1, *et seq*.

328. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

329. The Iowa Competition Law aims to "prohibit[] restraints of economic activity and monopolistic practices." IOWA CODE § 553.2.

330. Members of the class purchased Tracleer within the State of Iowa during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

331. Defendants attempted to establish or did in fact establish a monopoly for the purpose of excluding competition or controlling, fixing, or maintaining prices for Tracleer, in violation of Iowa Code § 553.1, *et seq*.

332. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Iowa, and are entitled to all forms of relief, including actual damages, exemplary damages for willful conduct, reasonable attorneys' fees and costs, and injunctive relief.

SIXTH CLAIM FOR RELIEF
VIOLATION OF MAINE'S ANTITRUST STATUTE
ME. REV. STAT. ANN. TIT. 10 § 1101, *et seq*.

333. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

334. Part 3 of Title 10 of the Maine Revised Statutes generally governs regulation of trade in Maine. Chapter 201 thereof governs monopolies and profiteering, generally prohibiting contracts in restraint of trade and conspiracies to monopolize trade. ME. REV. STAT. ANN. tit. 10, §§ 1101-02.

335. Members of the class purchased Tracleer within the State of Maine during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

336. Under Maine law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. ME. REV. STAT. ANN. tit. 10, § 1104(1).

337. Defendants monopolized or attempted to monopolize the trade or commerce of bosentan within the intrastate commerce of Maine, in violation of ME. REV. STAT. ANN. tit. 10, § 1101, *et seq*.

338. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Maine and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' and experts' fees and costs.

SEVENTH CLAIM FOR RELIEF
VIOLATION OF MARYLAND'S ANTITRUST STATUTE
MD. CODE ANN. § 11-204(A), *et seq*.

339. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

340. Under Maryland law, any political subdivision organized under the authority of the State is entitled to bring an action for damages and an injunction under the antitrust statute. MD. CODE ANN. § 11-209(b)(1).

341. Maryland's antitrust statute makes it unlawful to, *inter alia*, "[m]onopolize, attempt to monopolize, or combine or conspire with one or more other persons to monopolize any part of the trade or commerce within the State, for the purpose of excluding competition or of controlling, fixing, or maintaining prices in trade or commerce." MD. CODE ANN. § 11-204(a)(2).

342. The purpose of Maryland's antitrust statute is "to complement the body of federal law governing restraints of trade, unfair competition, and unfair, deceptive, and fraudulent acts or practices." MD. CODE ANN. § 11-202(a)(1).

343. Defendants monopolized or attempted to monopolize the trade or commerce of Tracleer within the intrastate commerce of Maryland, in violation of Maryland Code § 204(a)(2), *et seq*.

344. Under Maryland's antitrust statute, a plaintiff who establishes a violation is entitled to recover three times the amount of actual damages resulting from the violation, along with costs and reasonably attorneys' fees. MD. CODE ANN. § 209(b)(4).

345. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Maryland and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' and experts' fees and costs.

EIGHTH CLAIM FOR RELIEF
VIOLATION OF MASSACHUSETTS
MASS. GEN. LAWS CH. 93A, § 1, *et seq*.

346. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

347. By reason of the conduct alleged herein, including the violation of federal antitrust laws, Defendants have violated the Massachusetts Consumer Protection Act, Massachusetts General Laws ch. 93A § 1, *et seq*.

348. Members of the class purchased Tracleer within the Commonwealth of Massachusetts during the class period. But for Defendants' conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

349. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Massachusetts, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

350. Defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the Commonwealth of Massachusetts.

351. Defendants' unlawful conduct substantially affected Massachusetts' trade and commerce.

352. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

353. By reason of the foregoing, Plaintiffs and the class are entitled to seek all forms of relief, including up to treble damages and reasonable attorney's fees and costs under Massachusetts General Laws ch. 93A § 9.

354. While Plaintiffs believe that the notice requirements of Massachusetts General Laws ch. 93A § 9 does not apply to Defendants as they do not maintain a place of business in the Commonwealth, out of an abundance of caution, Plaintiffs mailed to all Defendants on November 19, 2018, via certified mail, return receipt requested, demand letters detailing the unfair acts, the injury suffered, and the relief requested from Defendants.

NINTH CLAIM FOR RELIEF
VIOLATION OF THE MICHIGAN ANTITRUST REFORM ACT
MICH. COMP. LAWS § 445.771, *et seq*.

355. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

356. The Michigan Antitrust Reform Act aims "to prohibit contracts, combinations, and conspiracies in restraint of trade or commerce . . . to prohibit monopolies and attempts to monopolize trade or commerce . . . [and] to provide remedies, fines, and penalties for violations of this act." Mich. Act 274 of 1984 (MICH. COMP. LAWS § 445.771, *et seq.*).

357. Members of the class purchased Tracleer within the State of Michigan during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

358. Under the Michigan Antitrust Reform Act, indirect purchasers have standing to maintain an action based on the facts alleged in this complaint. MICH. COMP. LAWS § 445.778(2).

359. Defendants established, maintained, or used, or attempted to establish, maintain, or use, a monopoly of trade or commerce in violation of Michigan Compiled Laws §445.773.

360. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Michigan and are entitled to all forms of relief, including actual damages, treble damages for flagrant violations, interest, costs, reasonable attorneys' fees, and injunctive or other appropriate equitable relief.

TENTH CLAIM FOR RELIEF
VIOLATION OF THE MINNESOTA ANTITRUST LAW,
MINN. STAT. §§ 325D.49, *et seq.* & 325D.57, *et seq.*

361. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

362. The Minnesota Antitrust Law of 1971 aims to prohibit "any contract, combination or conspiracy when any part thereof was created, formed, or entered into in [Minnesota]; and any contract, combination or conspiracy, wherever created, formed or entered into; any establishment, maintenance or use of monopoly power; and any attempt to establish, maintain or use monopoly power, whenever any of the forgoing affects the trade or commerce of [Minnesota]." MINN. STAT. § 325D.54.

363. Members of the class purchased Tracleer within the State of Minnesota during the class period. But for Defendants' conduct set forth herein, the price of bosentan would have been lower, in an amount to be determined at trial.

364. Under the Minnesota Antitrust Act of 1971, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. MINN. STAT. § 325D.57.

365. Defendants established, maintained, used or attempted to establish, maintain or use monopoly power over the trade or commerce in the market for bosentan within the intrastate commerce of and outside of Minnesota; and fixed prices and allocated markets for Tracleer within the intrastate commerce of and outside of Minnesota, in violation of Minn. Stat. § 325D.49, *et seq*.

366. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Minnesota and are entitled to all forms of relief, including actual damages, treble damages, costs and disbursements, reasonable attorneys' fees, and injunctive relief necessary to prevent and restrain violations hereof.

ELEVENTH CLAIM FOR RELIEF
VIOLATION OF THE MISSISSIPPI ANTITRUST STATUTE,
MISS. CODE ANN. § 75-21-1, *et seq*.

367. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

368. Title 75 of the Mississippi Code regulates trade, commerce and investments. Chapter 21 thereof generally prohibits trusts and combines in restraint or hindrance of trade, with the aim that "trusts and combines may be suppressed, and the benefits arising from competition in business [are] preserved" to Mississippians. MISS. CODE ANN. § 75-21-39.

369. "A trust or combine is a combination, contract, understanding or agreement, express or implied . . . when inimical to the public welfare" and with the effect of, *inter alia*, restraining trade, increasing the price or output of a commodity, or hindering competition in the production or sale of a commodity. MISS. CODE ANN. § 75-21-1.

370. Members of the class purchased Tracleer within the State of Mississippi during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

371. Under Mississippi law, indirect purchasers have standing to maintain an action under the antitrust provisions of the Mississippi Code based on the facts alleged in this Complaint. MISS. CODE ANN. § 75-21-9.

372. Defendants monopolized or attempted to monopolize the production, control or sale of bosentan, in violation of Mississippi Code § 75-21-3, *et seq*.

373. Tracleer is sold indirectly via distributors throughout the State of Mississippi. During the class period, Defendants' illegal conduct substantially affected Mississippi commerce.

374. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Mississippi and are entitled to all forms of relief, including actual damages and a penalty of $500 per instance of injury.

TWELFTH CLAIM FOR RELIEF
VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT,
MO. ANN. STAT. § 407.010, *et seq*.

375. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

376. Chapter 407 of the Missouri Merchandising Practices Act (the "MMPA") generally governs unlawful business practices, including antitrust violations such as restraints of trade and monopolization.

377. Members of the class purchased Tracleer within the State of Missouri during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

378. Under Missouri law, indirect purchasers have standing to maintain an action under the MMPA based on the facts alleged in this Complaint. *Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669 (Mo. 2007).

379. Defendants monopolized or attempted to monopolize the market for bosentan within the intrastate commerce of Missouri by possessing monopoly power in the market and willfully maintaining that power through agreements to fix prices, allocate markets and otherwise control trade, in violation of Missouri Statutes § 407.010, *et seq*.

380. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Missouri and are entitled to all forms of relief, including actual damages or liquidated damages in an amount which bears a reasonable relation to the actual damages which have been sustained, as well as reasonable attorneys' fees, costs, and injunctive relief.

THIRTEENTH CLAIM FOR RELIEF
VIOLATION OF THE NEBRASKA JUNKIN ACT,
NEB. REV. STAT. § 59-801, *et seq*.

381. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

382. Chapter 59 of the Nebraska Revised Statutes generally governs business and trade practices. Sections 801 through 831 thereof, known as the Junkin Act, prohibit antitrust violations such as restraints of trade and monopolization.

383. Members of the class purchased Tracleer within the State of Nebraska during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

384. Under Nebraska law, indirect purchasers have standing to maintain an action under the Junkin Act based on the facts alleged in this Complaint. NEB. REV. STAT. § 59-821.

385. Defendants monopolized or attempted to monopolize the market for Tracleer within the intrastate commerce of Nebraska by possessing monopoly power in the market and willfully maintaining that power through agreements to fix prices, allocate markets, and otherwise control trade, in violation of Nebraska Statutes § 59-801, *et seq*.

386. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Nebraska and are entitled to all forms of relief, including actual damages or liquidated damages in an amount which bears a reasonable relation to the actual damages which have been sustained, as well as reasonable attorneys' fees, costs, and injunctive relief.

FOURTEENTH CLAIM FOR RELIEF
VIOLATION OF THE NEVADA UNFAIR TRADE PRACTICES ACT,
NEV. REV. STAT. § 598A.010, *et seq*.

387. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

388. The Nevada Unfair Trade Practice Act ("NUTPA") states that "free, open and competitive production and sale of commodities . . . is necessary to the economic well-being of the citizens of the State of Nevada." NEV. REV. STAT. § 598A.030(1).

389. The policy of NUTPA is to "[p]rohibit acts in restraint of trade or commerce . . . [to [p]reserve and protect the free, open and competitive market . . . [and to] [p]enalize all persons engaged in [] anticompetitive practices." NEV. REV. STAT. § 598A.030(2). Such acts include, *inter alia*, price fixing, division of markets, allocation of customers, and monopolization of trade. NEV. REV. STAT. § 598A.060.

390. Members of the class purchased Tracleer within the State of Nevada during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

391. Under Nevada law, indirect purchasers have standing to maintain an action under NUTPA based on the facts alleged in this Complaint. NEV. REV. STAT. § 598A.210(2).

392. Defendants monopolized or attempted to monopolize trade or commerce of bosentan within the intrastate commerce of Nevada, in violation of Nevada Statutes § 598A.010, *et seq*.

393. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Nevada in that numerous sales of Defendants' Tracleer took place in Nevada, purchased by Nevada consumers at supra-competitive prices caused by Defendants' conduct.

394. Accordingly, Plaintiffs and members of the class are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, costs, and injunctive relief.

395. In accordance with the requirements of Section 598A.210(3), notice of this action was mailed to the Nevada Attorney General by Plaintiffs.

FIFTEENTH CLAIM FOR RELIEF
VIOLATION OF NEW HAMPSHIRE'S ANTITRUST STATUTE,
N.H. REV. STAT. ANN. § 356, *et seq*.

396. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

397. Title XXXI of the New Hampshire Statutes generally governs trade and commerce. Chapter 356 thereof governs combinations and monopolies and prohibits restraints of trade. N.H. REV. STAT. ANN. §§ 356:2, 3.

398. Members of the class purchased Tracleer within the State of New Hampshire during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

399. Under New Hampshire law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.H. REV. STAT. ANN. § 356:11(II).

400. Defendants established, maintained or used monopoly power, or attempted to, in violation of New Hampshire Revised Statutes § 356:1, *et seq*.

401. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in New Hampshire and are entitled to all forms of relief, including actual damages

sustained, treble damages for willful or flagrant violations, reasonable attorneys' fees, costs, and injunctive relief.

SIXTEENTH CLAIM FOR RELIEF
VIOLATION OF THE NEW MEXICO ANTITRUST ACT,
N.M. STAT. ANN. § 57-1-1, *et seq*.

402. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

403. The New Mexico Antitrust Act aims to "prohibit[] restraints of trade and monopolistic practices." N.M. STAT. ANN. § 57-1-15.

404. Members of the class purchased Tracleer within the State of New Mexico during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

405. Under New Mexico law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.M. STAT. ANN. § 57-1-3.

406. Defendants monopolized or attempted to monopolize trade for bosentan within the intrastate commerce of New Mexico, in violation of New Mexico Statutes §§ 57-1-1 and 57-1-2, *et seq*.

407. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in New Mexico and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, costs, and injunctive relief.

SEVENTEENTH CLAIM FOR RELIEF
VIOLATION OF SECTION 340 OF THE NEW YORK GENERAL BUSINESS LAW N.Y. GEN. BUS. LAW § 340, *et seq*.

408. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

409. Section 340 of Article 22 of the New York General Business Law general prohibits monopolies and contracts or agreements in restraint of trade, with the policy of encouraging competition or the free exercise of any activity in the conduct of any business, trade or commerce in New York. N.Y. GEN. BUS. LAW § 340(1).

410. Members of the class purchased Tracleer within the State of New York during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

411. Under New York law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.Y. GEN. BUS. LAW § 340(6).

412. Defendants established or maintained a monopoly within the intrastate commerce of New York for the trade or commerce of Tracleer and restrained competition in the free exercise of the conduct of the business of Tracleer within the intrastate commerce of New York, in violation of New York General Business Law § 340, *et seq*.

413. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in New York and are entitled to all forms of relief, including actual damages, treble damages, costs not exceeding $10,000, and reasonable attorneys' fees and all relief available under N.Y. GEN. BUS. LAW §349, *et seq*.

EIGHTEENTH CLAIM FOR RELIEF
VIOLATION OF THE NORTH CAROLINA GENERAL STATUTES,
N.C. GEN. STAT. § 75-1, *et seq*.

414. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

415. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, for the purpose of affecting competition

or controlling, fixing, or maintaining prices, a substantial part of which occurred within North Carolina.

416. Defendants' unlawful conduct substantially affected North Carolina's trade and commerce.

417. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

418. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available, including treble damages, under North Carolina General Statutes § 75-1, *et seq*.

NINETEENTH CLAIM FOR RELIEF
VIOLATION OF THE NORTH DAKOTA UNIFORM STATE ANTITRUST ACT, N.D. CENT. CODE § 51-08.1-01, *et seq*.

419. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

420. The North Dakota Uniform State Antitrust Act generally prohibits restraints on or monopolization of trade. N.D. CENT. CODE § 51-08.1-01, *et seq*.

421. Members of the class purchased Tracleer within the State of North Dakota during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

422. Under the North Dakota Uniform State Antitrust Act, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.D. CENT. CODE § 51-08.1-08.

423. Defendants established, maintained, or used a monopoly, or attempted to do so, for the purposes of excluding competition or controlling, fixing or maintaining prices for bosentan, in violation of North Dakota Century Code §§ 51-08.1-02, 03.

424. Plaintiffs and members of the class were injured with respect to purchases in North Dakota and are entitled to all forms of relief, including actual damages, treble damages for flagrant violations, costs, reasonable attorneys' fees, and injunctive or other equitable relief.

TWENTIETH CLAIM FOR RELIEF
VIOLATION OF THE OREGON ANTITRUST LAW,
OR. REV. STAT. § 646.705, *et seq*.

425. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

426. Chapter 646 of the Oregon Revised Statutes generally governs business and trade practices within Oregon. Sections 705 through 899 thereof govern antitrust violations, with the policy to "encourage free and open competition in the interest of the general welfare and economy of the state." OR. REV. STAT. § 646.715.

427. Members of the class purchased Tracleer within the State of Oregon during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

428. Under Oregon law, indirect purchasers have standing under the antitrust provisions of the Oregon Revised Statutes to maintain an action based on the facts alleged in this Complaint. OR. REV. STAT. § 646.780(1)(a).

429. Defendants monopolized or attempted to monopolize the trade or commerce of Tracleer, in violation of Oregon Revised Statutes § 646.705, *et seq*.

430. Plaintiffs and members of the class were injured with respect to purchases of Tracleer within the intrastate commerce of Oregon, or alternatively to interstate commerce

involving actual or threatened injury to persons located in Oregon, and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, expert witness fees and investigative costs, and injunctive relief.

TWENTY-FIRST CLAIM FOR RELIEF
VIOLATION OF THE PUERTO RICAN ANTI-MONOPOLY ACT,
P.R. LAWS TIT. 10, § 260, *et seq*.

431. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

432. The provisions of the Puerto Rican Anti-Monopoly Act of 1964 (the AMA) parallel Sections 1 and 2 of the Sherman Act, and other federal statutes. And those provisions are supplemented by The Regulation on Fair Competition Number VII, which proscribes certain conduct including the type engaged in by Defendants more fully described above.

433. Under the AMA, it is unlawful to monopolize, or attempt to monopolize any part of the trade or commerce in the Commonwealth of Puerto Rico. P.R. LAWS tit. 10, § 260.

434. Members of the class purchased Tracleer within Puerto Rico during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

435. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available, including treble damages, attorneys' fees, and costs of suit Puerto Rico Laws tit. 10, § 268.

TWENTY-SECOND CLAIM FOR RELIEF
VIOLATION OF THE RHODE ISLAND ANTITRUST ACT,
6 R.I. GEN. LAWS § 6-36-1, *et seq*.

436. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

437. The Rhode Island Antitrust Act aims "[t]o promote the unhampered growth of commerce and industry throughout [Rhode Island] by prohibiting unreasonable restraints of trade and monopolistic practices" that hamper, prevent or decrease competition. 6 R.I. GEN. LAWS § 636-2(a)(2).

438. Members of the class purchased Tracleer within the State of Rhode Island during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

439. Defendants established, maintained or used, or attempted to establish, maintain or use, a monopoly in the trade of bosentan for the purpose of excluding competition or controlling, fixing or maintaining prices within the intrastate commerce of Rhode Island, in violation of 6 Rhode Island General Laws § 6-36-1, *et seq*.

440. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Rhode Island and are entitled to all forms of relief, including actual damages, treble damages, reasonable costs, reasonable attorneys' fees, and injunctive relief.

TWENTY-THIRD CLAIM FOR RELIEF
VIOLATION OF THE SOUTH DAKOTA ANTITRUST STATUTE,
S.D. CODIFIED LAWS § 37-1-3.1, *et seq*.

441. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

442. Chapter 37-1 of the South Dakota Codified Laws prohibits restraint of trade, monopolies and discriminatory trade practices. S.D. CODIFIED LAWS §§ 37-1-3.1, 3.2.

443. Members of the class purchased Tracleer within the State of South Dakota during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

444. Under South Dakota law, indirect purchasers have standing under the antitrust provisions of the South Dakota Codified Laws to maintain an action based on the facts alleged in this Complaint. S.D. CODIFIED LAWS § 37-1-33.

445. Defendants monopolized or attempted to monopolize trade or commerce of bosentan within the intrastate commerce of South Dakota, in violation of South Dakota Codified Laws § 37-1, *et seq*.

446. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in South Dakota and are entitled to all forms of relief, including actual damages, treble damages, taxable costs, reasonable attorneys' fees, and injunctive or other equitable relief.

TWENTY-FOURTH CLAIM FOR RELIEF
VIOLATION OF THE UTAH ANTITRUST ACT,
UTAH CODE ANN. § 76-10-3101, *et seq*.

447. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this Complaint.

448. The Utah Antitrust Act aims to "encourage free and open competition in the interest of the general welfare and economy of this state by prohibiting monopolistic and unfair trade practices, combinations and conspiracies in restraint of trade or commerce . . . ." UTAH CODE ANN. § 76-10-3102.

449. Members of the class purchased Tracleer within the State of Utah during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

450. Under the Utah Antitrust Act, indirect purchasers who are either Utah residents or Utah citizens have standing to maintain an action based on the facts alleged in this Complaint. UTAH CODE ANN. § 76-10-3109(1)(a).

451. Defendants monopolized or attempted to monopolize trade or commerce of bosentan, in violation of Utah Code § 76-10-3101, *et seq*.

452. Plaintiffs and members of the class who are either Utah residents or Utah citizens were injured with respect to purchases of Tracleer in Utah and are entitled to all forms of relief, including actual damages, treble damages, costs of suit, reasonable attorneys' fees, and injunctive relief.

TWENTY-FIFTH CLAIM FOR RELIEF
VIOLATION OF THE WEST VIRGINIA ANTITRUST ACT,
W. VA. CODE § 47-18-1, *et seq*.

453. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

454. The violations of federal antitrust law set forth above also constitute violations of Section 47-18-1 of the West Virginia Code.

455. During the class period, Defendants engaged in anticompetitive conduct alleged above, including the establishment or maintenance of a monopoly for the purpose of excluding competition, in violation of W. VA. CODE § 47-18-4.

456. Defendants' anticompetitive acts described above were knowing, willful and constitute violations or flagrant violations of the West Virginia Antitrust Act.

457. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the class have been injured in their business and property in that they paid more for Tracleer than they otherwise would have paid in the absence of Defendants' unlawful conduct.

458. Members of the class have standing to pursue their claims under, *inter alia*, West Virginia Code § 47-18-9.

459. As a result of Defendants' violation of Section 47-18-3 of the West Virginia Antitrust Act, plaintiffs and members of the class seek treble damages and their cost of suit, including reasonable attorneys' fees, pursuant to Section 47-18-9 of the West Virginia Code.

TWENTY-SIXTH CLAIM FOR RELIEF
VIOLATION OF THE WISCONSIN ANTITRUST ACT,
WIS. STAT. § 133.01, *et seq*.

460. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

461. Chapter 133 of the Wisconsin Statutes governs trust and monopolies, with the intent "to safeguard the public against the creation or perpetuation of monopolies and to foster and encourage competition by prohibiting unfair and discriminatory business practices which destroy or hamper competition." WIS. STAT. § 133.01.

462. Members of the class purchased Tracleer within the State of Wisconsin during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

463. Under Wisconsin law, indirect purchasers have standing under the antitrust provisions of the Wisconsin Statutes to maintain an action based on the facts alleged in this Complaint. WIS. STAT. § 133.18(1)(a).

464. Defendants monopolized or attempted to monopolize the trade or commerce of bosentan, with the intention of injuring or destroying competition therein, in violation of Wisconsin Statutes § 133.01, *et seq*.

465. Plaintiffs and members of the class were injured with respect to purchases of Tracleer in Wisconsin in that the actions alleged herein substantially affected the people of Wisconsin, with at least thousands of consumers in Wisconsin paying substantially higher prices for Defendants' Tracleer in Wisconsin.

466. Accordingly, Plaintiffs and members of the class are entitled to all forms of relief, including actual damages, treble damages, costs and reasonable attorneys' fees, and injunctive relief.

467. Defendants' anticompetitive activities have directly, foreseeably, and proximately caused injury to Plaintiffs and members of the class in the United States. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced Tracleer from Defendants, (2) paying higher prices for Tracleer than they would have in the absence of Defendants' conduct, and (3) being denied the opportunity to purchase generic bosentan at a price substantially lower than what they were forced to pay for Tracleer. These injuries are of the type of the laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

468. Defendants are jointly and severally liable for all damages suffered by Plaintiffs and members of the classes.

VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

469. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

470. Defendants' above-described scheme and conduct constitutes unfair competition, unconscionable conduct, and deceptive acts and practices in violation of the state consumer protection statutes set forth below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, and/or unconscionable acts or practices, Plaintiffs and the class were both denied the opportunity to purchase lower-priced generic versions of bosentan and paid higher prices for Tracleer than they should have.

471. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and class members could not reasonably have avoided injury from Defendants' wrongful conduct.

472. Plaintiffs and members of the class purchased goods, namely Tracleer, primarily for personal, family, or household purposes.

473. There was and is a gross disparity between the price that Plaintiffs and the class members paid for Tracleer and the value they received.

474. The following twenty-seventh through forty-sixth claims for relief are pleaded under the consumer protection or similar laws of each State or jurisdiction identified below, on behalf of the class.

TWENTY-SEVENTH CLAIM FOR RELIEF
VIOLATION OF ARIZONA CONSUMER FRAUD ACT
ARIZ. REV. STAT. § 44-1521, *et seq*.

475. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

476. The Arizona Consumer Fraud Act prohibits the "act, use or employment by any person of any deception, deceptive . . . act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise." ARIZ. REV. STAT. § 44-1522(A)

477. By reason of the conduct alleged herein, including the violation of federal antitrust laws, Defendants have violated the Arizona Consumer Fraud Act, Section 44-1521, *et seq*.

478. Members of the class purchased Tracleer within the State of Arizona during the class period. But for Defendants' conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

479. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred

within Arizona, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

480. Defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Arizona.

481. Defendants' unlawful conduct substantially affected Arizona's trade and commerce.

482. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

483. By reason of the foregoing, Plaintiffs and the class are entitled to seek all forms of relief, including up to treble damages and reasonable attorneys' fees and costs.

TWENTY-EIGHTH CLAIM FOR RELIEF
VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW
CAL. BUS. & PROF. CODE § 17200, *et seq*. (THE "UCL")

484. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

485. The violations of federal antitrust law set forth above also constitute violations of Section 17200, *et seq.* of the California Business and Professions Code.

486. Defendants have engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the UCL by engaging in the acts and practices specified above.

487. This claim is instituted pursuant to Sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from these Defendants for acts, as alleged herein, that violated the UCL.

488. Defendants' conduct as alleged herein violated the UCL. The acts, omissions, misrepresentations, practices and non-disclosures of defendants, as alleged herein, including their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer, constituted a common, continuous, and continuing course of conduct of unfair competition by means of unfair, unlawful, and/or fraudulent business acts or practices within the meaning of the UCL, including, but not limited to, the violations of Section 16720, *et seq.*, of California Business and Professions Code, set forth above.

489. Defendants' acts, omissions, misrepresentations, practices, and non- disclosures, as described above, whether or not in violation of Section 16720, *et seq.*, of California Business and Professions Code, and whether or not concerted or independent acts, are otherwise unfair, unconscionable, unlawful or fraudulent.

490. Plaintiffs and members of the class are entitled to, *inter alia*, full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by defendants as a result of such business acts or practices.

491. The unlawful and unfair business practices of Defendants, and each of them, as described above, have caused and continue to cause members of the class to pay supra-competitive and artificially-inflated prices for Tracleer sold in the State of California. Plaintiff and the members of the class suffered injury in fact and lost money or property as a result of such unfair competition.

492. As alleged in this complaint, Defendants have been unjustly enriched as a result of their wrongful conduct and by Defendants' unfair competition. Plaintiff and the members of the class are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Defendants

as a result of such business practices, pursuant to California Business and Professions Code Sections 17203 and 17204.

TWENTY-NINTH CLAIM FOR RELIEF
VIOLATION OF THE DISTRICT OF COLUMBIA CONSUMER PROTECTION PROCEDURES ACT, D.C. CODE § 28-3901, *et seq*.

493. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

494. Members of the class purchased Tracleer for personal, family, or household purposes.

495. By reason of the conduct alleged herein, including their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer, Defendants have violated D.C. Code § 28-3901, *et seq.*

496. Defendants are "merchants" within the meaning of D.C. Code § 28- 3901(a)(3).

497. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within the District of Columbia, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

498. Defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the District of Columbia.

499. Defendants' unlawful conduct substantially affected the District of Columbia's trade and commerce.

500. As a direct and proximate cause of defendants' unlawful conduct, Plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

501. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief, including treble damages or $1500 per violation (whichever is greater) plus punitive damages, reasonable attorney's fees and costs under D.C. Code § 28-3901, *et seq.*

THIRTIETH CLAIM FOR RELIEF
VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT,
FLA. STAT. § 501.201(2), *et seq.*

502. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

503. The Florida Deceptive & Unfair Trade Practices Act, Florida Statutes § 501.201, *et seq.* (the "FDUTPA"), generally prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce," including practices in restraint of trade. FLA. STAT. § 501.204(1).

504. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." FLA. STAT. § 501.202(2).

505. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

506. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this complaint. FLA. STAT. § 501.211(1) ("anyone aggrieved by a violation of this [statute] may bring an action . . .").

507. Members of the class purchased Tracleer within the State of Florida during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

508. Defendants established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for bosentan, for the purpose of excluding competition or controlling, fixing or maintaining prices in Florida at a level higher than the competitive market level, beginning at least as early as 2015 and continuing through the date of this filing.

509. Accordingly, Defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Florida.

510. Defendants' unlawful conduct substantially affected Florida's trade and commerce.

511. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property by virtue of overcharges for Tracleer and are threatened with further injury.

512. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including injunctive relief pursuant to Florida Statutes § 501.208 and declaratory judgment, actual damages, reasonable attorneys' fees and costs pursuant to Florida Statutes § 501.211.

THIRTY-FIRST CLAIM FOR RELIEF
VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT,
815 ILL. COMP. STAT. ANN. 505/10A, *et seq*.

513. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

514. By reason of the conduct alleged herein, Defendants have violated 740 Illinois Compiled Statutes 10/3(1), *et seq*.

515. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the relevant market, a substantial part of which occurred

within Illinois, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

516. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Illinois.

517. Defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to Plaintiffs and members of the class.

518. Defendants' unlawful conduct substantially affected Illinois's trade and commerce.

519. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and members of the class were actually deceived and have been injured in their business or property and are threatened with further injury.

520. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages or any other relief the Court deems proper under 815 Illinois Compiled Statutes 505/10a, *et seq*.

THIRTY-SECOND CLAIM FOR RELIEF
VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT, MASS. GEN. LAWS. CH. 93A § 1, *et seq*.

521. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

522. By reason of the conduct alleged herein, including the violation of federal antitrust laws, Defendants have violated the Massachusetts Consumer Protection Act, Massachusetts General Laws ch. 93A § 2, *et seq*.

523. Members of the class purchased Tracleer within the Commonwealth of Massachusetts during the class period. But for Defendants' conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

524. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Massachusetts, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

525. Defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the Commonwealth of Massachusetts.

526. Defendants' unlawful conduct substantially affected Massachusetts' trade and commerce.

527. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

528. By reason of the foregoing, Plaintiffs and the class are entitled to seek all forms of relief, including up to treble damages and reasonable attorney's fees and costs under Massachusetts General Laws ch. 93A § 9.

529. Pursuant to Massachusetts General Laws ch. 93A § 9, Plaintiffs mailed to all Defendants on November 19, 2018, via certified mail, return receipt requested, demand for payment letters which explained the unfair acts, the injury suffered, and requested relief from the Defendants.

THIRTY-THIRD CLAIM FOR RELIEF
VIOLATION OF THE MINNESOTA CONSUMER FRAUD ACT,
MINN. STAT. § 325F.68, *et seq*.

530. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

531. By reason of the conduct alleged herein, Defendants have violated Minnesota Statutes § 325F.68, *et seq*.

532. Defendants engaged in a deceptive trade practice with the intent to injure competitors and consumers through supra-competitive profits.

533. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Minnesota, for the purpose of controlling, fixing, or maintaining prices in the bosentan market.

534. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Minnesota.

535. Defendants' conduct, specifically in their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer, created a fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

536. Defendants' unlawful conduct substantially affected Minnesota's trade and commerce.

537. Defendants' conduct was willful.

538. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

539. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs under Minnesota Statutes § 325F.68, *et seq.* and applicable case law.

THIRTY-FOURTH CLAIM FOR RELIEF
VIOLATION OF THE MONTANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT OF 1970,
MONT. CODE, §§ 30-14-103, *et seq.*, AND §§ 30-14-201, *et seq*.

540. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

541. Defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Montana Code, §§ 30-14-103, *et seq.*, and 30-14-201, *et seq*.

542. Defendants' unlawful conduct had the following effects: (1) Tracleer price competition was restrained, suppressed, and eliminated throughout Montana; (2) Tracleer prices were raised, fixed, maintained, and stabilized at artificially high levels throughout Montana; (3) Plaintiffs and members of the class were deprived of free and open competition; and (4) Plaintiffs and members of the class paid supra-competitive, artificially inflated prices for Tracleer.

543. During the class period, Defendants' illegal conduct substantially affected Montana commerce and consumers.

544. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the class have been injured and are threatened with further injury. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Montana Code, §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*, and, accordingly, Plaintiffs and members of the class seek all relief available under that statute.

THIRTY-FIFTH CLAIM FOR RELIEF
VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT,
NEB. REV. STAT. § 59-1602, *et seq*.

545. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

546. By reason of the conduct alleged herein, Defendants have violated Nebraska Revised Statutes § 59-1602, *et seq*.

547. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Nebraska.

548. Defendants' conduct was conducted with the intent to deceive Nebraska consumers regarding the nature of Defendants' actions within the stream of Nebraska commerce.

549. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nebraska.

550. Defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon Plaintiffs and members-of-the-class' ability to protect themselves.

551. Defendants' unlawful conduct substantially affected Nebraska's trade and commerce.

552. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

553. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief available under Nebraska Revised Statutes § 59- 1614.

THIRTY-SIXTH CLAIM FOR RELIEF
VIOLATION OF THE NEVADA DECEPTIVE TRADE PRACTICES ACT,
NEV. REV. STAT. § 598.0903, *et seq*.

554. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

555. By reason of the conduct alleged herein, Defendants have violated Nevada Revised Statutes § 598.0903, *et seq*.

556. Defendants engaged in a deceptive trade practice with the intent to injure competitors and to substantially lessen competition.

557. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Nevada, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

558. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nevada.

559. Defendants' conduct, including their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer, amounted to a fraudulent act or practice committed by a supplier in connection with a consumer transaction.

560. Defendants' unlawful conduct substantially affected Nevada's trade and commerce.

561. Defendants' conduct was willful.

562. As a direct and proximate cause of Defendants' unlawful conduct, the members of the class have been injured in their business or property and are threatened with further injury.

563. By reason of the foregoing, the class is entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs, and a civil penalty of up to $5,000 per violation under Nevada Revised Statutes § 598.0993.

THIRTY-SEVENTH CLAIM FOR RELIEF
VIOLATION OF THE NEW HAMPSHIRE CONSUMER PROTECTION ACT,
N.H. REV. STAT. ANN. § 358-A:1, *et seq.*

564. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

565. By reason of the conduct alleged herein, defendants have violated New Hampshire Revised Statutes § 358-A:1, *et seq*.

566. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Tracleer market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within New Hampshire.

567. Defendants' conduct was conducted with the intent to deceive New Hampshire consumers regarding the nature of Defendants' actions within the stream of New Hampshire commerce.

568. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of New Hampshire.

569. Defendants' conduct was willful and knowing.

570. Defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon Plaintiffs' and members of the class' ability to protect themselves.

571. Defendants' unlawful conduct substantially affected New Hampshire's trade and commerce.

572. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

573. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief available under New Hampshire Revised Statutes §§ 358-A:10 and 358-A:10-a.

THIRTY-EIGHTH CLAIM FOR RELIEF
VIOLATION OF THE NEW MEXICO UNFAIR PRACTICES ACT,
N.M. STAT. ANN. § 57-12-1, *et seq*.

574. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

575. By reason of the conduct alleged herein, Defendants have violated New Mexico Statutes § 57-12-3, *et seq*.

576. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the relevant markets, a substantial part of which occurred within New Mexico, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

577. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of New Mexico.

578. Defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to Plaintiffs and members of the class.

579. Defendants' unlawful conduct substantially affected New Mexico's trade and commerce.

580. Defendants' conduct constituted "unconscionable trade practices" in that such conduct, inter alia, resulted in a gross disparity between the value received by the New Mexico class members and the price paid by them for Tracleer as set forth in New Mexico Statutes § 57-12-2E.

581. Defendants' conduct was willful.

582. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

583. By reason of the foregoing, Plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages or up to $300 per violation, whichever is greater, plus reasonable attorney's fees under New Mexico Statutes § 57-12-10.

THIRTY-NINTH CLAIM FOR RELIEF
VIOLATION OF THE NORTH CAROLINA UNFAIR TRADE AND BUSINESS PRACTICES ACT,
N.C. GEN. STAT. § 75-1.1, *et seq*.

584. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

585. By reason of the conduct alleged herein, Defendants have violated North Carolina General Statutes § 75-1.1, *et seq*.

586. Defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of North Carolina.

587. Defendants' trade practices are and have been immoral, unethical, unscrupulous, and substantially injurious to consumers.

588. Defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to Plaintiffs and members of the class.

589. Defendants' unlawful conduct substantially affected North Carolina's trade and commerce.

590. Defendants' conduct constitutes consumer-oriented deceptive acts or practices within the meaning of North Carolina law, which resulted in consumer injury and broad adverse

impact on the public at large and harmed the public interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

591. As a direct and proximate cause of Defendants' unlawful conduct, the Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

592. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including treble damages under North Carolina General Statutes § 75-16.

FORTIETH CLAIM FOR RELIEF
VIOLATION OF THE OREGON UNLAWFUL TRADE PRACTICES ACT,
OR. REV. STAT. § 646.605, *et seq*.

593. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

594. By reason of the conduct alleged herein, Defendants have violated Oregon Revised Statutes § 646.608, *et seq*.

595. Defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the bosentan market, a substantial part of which occurred within Oregon.

596. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Oregon.

597. Defendants' conduct was conducted with the intent to deceive Oregon consumers regarding the nature of Defendants' actions within the stream of Oregon commerce.

598. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of Oregon.

599. Defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon Plaintiffs' and members of the class' ability to protect themselves.

600. Defendants' unlawful conduct substantially affected Oregon's trade and commerce.

601. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

602. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief available under Oregon Revised Statutes § 646.638.

603. Pursuant to Section 646.638 of the Oregon Unlawful Trade Practices Act, with the filing of this action, a copy of this complaint is being served upon the Attorney General of Oregon.

FORTY-FIRST CLAIM FOR RELIEF
VIOLATION OF THE RHODE ISLAND DECEPTIVE TRADE PRACTICES ACT, R.I. GEN. LAWS § 6-13.1-1, *et seq*.

604. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

605. By reason of the conduct alleged herein, defendants have violated Rhode Island General Laws § 6-13.1-1, *et seq*.

606. Defendants engaged in an unfair or deceptive act or practice with the intent to injure competitors and consumers through supra-competitive profits.

607. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Rhode Island, for the purpose of controlling, fixing, or maintaining prices in the bosentan market.

608. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of Rhode Island.

609. Defendants' conduct amounted to an unfair or deceptive act or practice committed by a supplier in connection with a consumer transaction.

610. Defendants' unlawful conduct substantially affected Rhode Island's trade and commerce.

611. Defendants' conduct was willful.

612. Defendants deliberately failed to disclose material facts to Plaintiffs and members of the class concerning Defendants' unlawful activities, including their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer.

613. Defendants' deception constitutes information necessary to Plaintiffs and members of the class relating to the cost of Tracleer purchased.

614. Plaintiffs and members of the class purchased goods, namely Tracleer, primarily for personal, family, or household purposes.

615. As a direct and proximate cause of Defendants' unlawful conduct, the plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

616. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including actual damages or $200 per violation, whichever is greater, and injunctive relief and punitive damages under Rhode Island General Laws § 6-13.1-5.2.

FORTY-SECOND CLAIM FOR RELIEF
VIOLATION OF THE SOUTH CAROLINA'S UNFAIR TRADE PRACTICES ACT, S.C. CODE ANN. §§ 39-5-10, *et seq*.

617. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

618. By reason of the conduct alleged herein, Defendants have violated South Carolina Code § 39-5-10, *et seq*.

619. Defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the bosentan market, a substantial part of which occurred within Oregon.

620. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within South Carolina.

621. Defendants' conduct was conducted with the intent to deceive South Carolina consumers regarding the nature of Defendants' actions within the stream of South Carolina commerce.

622. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of South Carolina.

623. Defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon Plaintiffs' and members of the class' ability to protect themselves.

624. Defendants' unlawful conduct substantially affected South Carolina trade and commerce.

625. Defendants' unlawful conduct substantially harmed the public interest of the State of South Carolina, as nearly all members of the public purchase and consume Tracleer.

FORTY-THIRD CLAIM FOR RELIEF
VIOLATION OF THE SOUTH DAKOTA DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION LAW,
S.D. CODIFIED LAWS § 37-24*, et seq*.

626. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

627. By reason of the conduct alleged herein, Defendants have violated South Dakota Codified Laws § 37-24-6.

628. Defendants engaged in a deceptive trade practice with the intent to injure competitors and consumers through supra-competitive profits.

629. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within South Dakota, for the purpose of controlling, fixing, or maintaining prices in the Tracleer market.

630. Defendants' conduct, including their refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer, was unfair, unconscionable, or deceptive within the conduct of commerce within the State of South Dakota.

631. Defendants' conduct amounted to a fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

632. Defendants' unlawful conduct substantially affected South Dakota's trade and commerce.

633. Defendants' conduct was willful.

634. As a direct and proximate cause of Defendants' unlawful conduct, the Plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

635. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including actual damages and injunctive relief under South Dakota Codified Laws § 37-24-31.

FORTY-FOURTH CLAIM FOR RELIEF
VIOLATION OF THE VERMONT CONSUMER FRAUD ACT
VT. STAT. ANN. TIT. 9, CH. 63 §2451, *et seq*.

636. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

637. Title 9 of the Vermont Statutes generally governs commerce and trade in Vermont. Chapter 63 thereof governs consumer protection and prohibits, *inter alia*, unfair methods competition, unfair and deceptive acts and practices, and antitrust violations such as restraints of trade and monopolization. VT. STAT ANN. tit. 9, § 2453(a).

638. Members of the class purchased Tracleer within the State of Vermont during the class period. But for Defendants' conduct set forth herein, the price of Tracleer would have been lower, in an amount to be determined at trial.

639. Under Vermont law, indirect purchasers have standing under the antitrust provisions of the Vermont Statutes to maintain an action based on the facts alleged in this complaint. Vt. Stat. Ann. tit. 9, § 2465(b).

640. 826. Defendants competed unfairly by restraining trade as set forth herein, in violation of Vermont Statutes tit. 9, § 2453, *et seq*.

641. Plaintiffs and members of the Classes were injured with respect to purchases of Tracleer in Vermont and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' fees

FORTY-FIFTH CLAIM FOR RELEIF
VIOLATION OF THE VIRGINIA CONSUMER PROTECTION ACT
VA. CODE ANN. § 59.1- 196, *et seq*.

642. Plaintiff incorporates each and every allegation set forth in the preceding paragraphs of this complaint.

643. By reason of the conduct alleged herein, Defendants have violated Virginia Code § 59.1- 196, *et seq*.

644. Defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the bosentan market, a substantial part of which occurred within Virginia, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the bosentan market.

645. Defendants' conduct caused or was intended to cause unfair methods of competition within the Commonwealth of Virginia.

646. Defendants' unlawful conduct substantially affected Virginia's trade and commerce.

647. As a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs and the members class have been injured in their business or property and are threatened with further injury.

648. By reason of the foregoing, Plaintiffs and the members of the class are entitled to seek all forms of relief, including actual damages, treble damages, plus reasonable attorney's fees under Virginia Code § 59.1-196, *et seq*.

FORTY-SIXTH CLAIM FOR RELIEF
VIOLATION OF THE WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT, W. VA. CODE § 46A-6-101, *et seq*.

649. Plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

650. The West Virginia Consumer Credit and Protection Act prohibits, *inter alia*, "unfair or deceptive acts or practices in the conduct of any trade or commerce." W. VA. CODE § 46A-6-104.

651. The violations of federal antitrust law set forth above also constitute violations of Section 46A-6-101, *et seq.* of the West Virginia Code.

652. During the class period, Defendants engaged in the unfair and deceptive conduct alleged above.

653. Defendants' unfair and deceptive acts described above were knowing, willful and constitute violations or flagrant violations of West Virginia law.

654. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the class have been injured in their business and property in that they paid more for Tracleer than they otherwise would have paid in the absence of Defendants' unlawful conduct.

655. As a result of Defendants' violation of Section 47-18-3 of the West Virginia Antitrust Act, Plaintiffs and members of the class seek all recoverable damages and their cost of suit, including reasonable attorneys' fees, pursuant to Sections 46A-5-101(a) and 46A-5-104 of the West Virginia Code.

IX. COMPLIANCE WITH NOTICE REQUIREMENTS

656. In accordance with the requirements of Arizona Revised Statutes § 44-1415, Nevada Revised Statutes§ 598A.210(3), 5 Maine Revised Statutes§ 213(3), and New York

General Business Law § 340(5) counsel for plaintiffs has sent letters by certified mail, return receipt requested, to:

657. Mark Brnovich, Attorney General of Arizona;

658. Adam Laxalt, Attorney General of Nevada;

659. Janet Mills, Attorney General of Maine; and

660. Barbara Underwood, Attorney General of New York.

The letters informed them of the existence of this Class Action Complaint, identified the relevant state antitrust provisions, and enclosed a copy of the original complaints filed by plaintiffs.

Compliance with the Written Demand Requirements of West Virginia and Massachusetts

661. On November 19, 2018, counsel sent demand letters to Jane Griffiths, Global Head, Actelion Pharmaceuticals Ltd.; Actelion Clinical Research, Inc.; and Serge Messerlian, President, Actelion Pharmaceuticals US, Inc. These letters satisfy the requirements of West Virginia Code § 46A-6-106(c). The demand letter, which was sent via certified mail, return receipt requested, identified the claimants as "purchasers of Tracleer" in individual and representative capacities; described the unfair or deceptive acts or practices committed by Actelion; described the injury suffered (increased prices for Tracleer because of Actelion's failure to provide samples to would-be generic competitors); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other sanctions); and requested an offer to cure within the statutorily prescribed time.

662. The demand letter requirement of Section 9 of Massachusetts General Laws Annotated Chapter 93A does not apply as to Actelion because, upon information and belief, Actelion has not identified a place of business or assets within Massachusetts. In an abundance of caution, however, Plaintiffs, on behalf of themselves and all others similarly situated, served on Actelion written demands for relief, as described in the prior paragraph, on November 19, 2018.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed class, pray for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and appoint Plaintiffs as the named representatives of the class;

2. Award a declaratory judgment that Actelion's actions in blocking and/or delaying prospective generic competitors' access to samples of Tracleer was done for illegal, anticompetitive purposes, was an unreasonable restraint of trade, and had anticompetitive effects on the U.S. market for bosentan in violation of the Sherman Act, § 2;

3. Grant permanent injunctive relief:

   a. enjoining Actelion from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of generic bosentan or other generic drugs; and

   b. requiring Actelion to take affirmative steps to dissipate the continuing effects of its prior unlawful conduct;

4. Award Plaintiffs and the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

5. Grant Plaintiffs and the class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Actelion's wrongful conduct;

6. Award Plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

7. Award such other and further relief as the Court deems just and proper.

XI. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury of all issues so triable.

July 8, 2021

/s/ Sharon K. Robertson

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CERTIFICATE OF SERVICE

I, Sharon K. Robertson, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's CM/ECF system. Those attorneys who are registered CM/ECF users may access these filings and notice of these filings will be sent to those parties by operation of the CM/ECF system. A courtesy copy of this filing will be mailed to the Office of the Clerk of the Court of the District of Maryland.

Dated: July 8, 2021

/s/ *Sharon K. Robertson*
Sharon K. Robertson